IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
APPLIES TO ALL CASES	:	NO. 1:17-MD-2804

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

February 19, 2019

- - -

Videotaped deposition of MICHAEL DiBELLO, taken pursuant to notice, was held at the offices of Locke Lord, LLP, 200 Vesey Street, New York, New York, beginning at 10:29 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

APPEARANCES:

MOTLEY RICE, LLC
BY: DONALD A. MIGLIORI, ESQ.
28 Bridgeside Boulevard
Mount Pleasant, South Carolina 29464
(843) 216-9000
Dmigliori@motleyrice.com
Representing the Plaintiffs

LOCKE LORD, LLP
BY: JOHN P. McDONALD, ESQ.
C. SCOTT JONES, ESQ.
2200 Ross Avenue
Suite 2800
Dallas, Texas 75201
(214) 740.8758
jpmcdonald@lockelord.com
sjones@lockelord.com
Representing Henry Schein, Inc. and the Witness

FARRELL FRITZ, P.C.
BY: KEVIN P. MULRY, ESQ.
400 RXR Plaza
Uniondale, New York 11556
(516) 227.0620
Kmulry@farrellfritz.com
Representing the Defendant, Cardinal Health

GIBBONS, P.C.
BY: PAUL E. ASFENDIS, ESQ.
One Pennsylvania Plaza
37th Floor
New York, New York 10119-3701
(212) 613.2067
pasfendis@gibbonslaw.com
Representing the Defendant, AmerisourceBergen

APPEARANCES: (Cont'd.)

COVINGTON & BURLING, LLP
BY: FREDERICK BENSON, ESQ.
850 Tenth Street, NW, Suite 586N
Washington, D.C. 20001
(202) 662-5516
fbenson@cov.com
Representing the Defendant, McKesson Corporation

TELEPHONIC/STREAMING APPEARANCES:

JONES DAY
BY: SHUBBA HARRIS, ESQ.
90 South Seventh Street, Suite 4950
Minneapolis, Minnesota 55402
(612) 217-8800
Shubbaharris@jonesday.com
Representing the Defendant, Walmart

MARCUS & SHAPIRA, LLP
BY: PAUL MANNIX, ESQ.
One Oxford Centre, 35th Floor
Pittsburgh, Pennsylvania 15219
(412) 338-4683
pmannix@marcus-shapira.com
Representing the Defendant, HBC Service Company

ARNOLD & PORTER KAYE SCHOLER, LLP
BY: TIFFANY IKEDA, ESQ.
BY: KAREN RIGBERG, ESQ.
777 Figueroa Street, 44th Floor
Los Angeles, California 90017
(213) 243-4000
tiffany.ikeda@arnoldporter.com
karen.rigberg@arnoldporter.com
Representing the Defendants, Endo Health Solutions; Endo Pharmaceuticals, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

APPEARANCES: (Cont'd.)

VIDEOTAPE TECHNICIAN:
Henry Marte

ALSO PRESENT:
Janine K. Downing, Esq. - (via telephone) (Henry Schein)

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I N D E X
- - -

Testimony of:

MICHAEL DiBELLO

By Mr. Migliori 14

- - -
E X H I B I T S
- - -

NO.	DESCRIPTION	PAGE
Henry Schein DiBello-1	Notice of Deposition	17
Henry Schein DiBello-2	Bio of Michael DiBello Aceto	25
Henry Schein DiBello-3	Henry Schein, Inc. Export Compliance Program Corporate Procedural Manual HSI-MDL-00170080-108	39

- - -
E X H I B I T S (Cont'd.)
- - -

NO. DESCRIPTION PAGE

Henry Schein
DiBello-4 Custodial File Of Michael DiBello HSI-MDL-00636179-51 55

Henry Schein
DiBello-5 Current DEA Challenges from a Distributor's Perspective 7th Annual Controlled Substance Conference (No Bates) 64

Henry Schein
DiBello-6 E-mail, 7/19/18 Subject, DEA Slides HSI-MDL-00433692 & Attachment DEA Compliance Processes: Follow the Order 76

Henry Schein
DiBello-7 Code of Federal Regulations 21 C.F.R. 1301.74 89

Henry Schein
DiBello-8 United States Code Title 21 21 USCA 801, 821 823 89

- - -
E X H I B I T S (Cont'd.)
- - -

NO. DESCRIPTION PAGE

Henry Schein
DiBello-9 E-mail Thread 1/5/07 Subject, Purging Control Drug Files HSI-MDL-00092254 93

Henry Schein
DiBello-10 Suspicious Monitoring System Meeting 10/10/07 HSI-MDL-00386726 109

Henry Schein
DiBello-11 Draft Summary of the HDMA Meeting October 16 - 17, 2007 Not for External Distribution HSI-MDL-00622468-72 127

Henry Schein
DiBello-12 Executive Summary HSI-MDL-00404203-09 137

Henry Schein
DiBello-13 US DOJ DEA Letter, 9/27/06 HSI-MDL-00387177-80 164

Henry Schein
DiBello-14 US DOJ DEA Letter, 2/7/07 HSI-MDL-00093112-15 171

- - -
E X H I B I T S (Cont'd.)
- - -

NO. DESCRIPTION PAGE

Henry Schein
DiBello-15 US DOJ DEA Letter, 12/27/07 HSI-MDL-00404079-80 174

Henry Schein
DiBello-16 Suspicious Monitoring System Specifications Draft HSI-MDL-00374284-85 175

Henry Schein
DiBello-17 Henry Schein Visit Overview HSI-MDL-00386875-79 186

Henry Schein
DiBello-18 New Account Issues Involving Controlled Substances HSI-MDL-00231217-18 191

Henry Schein
DiBello-19 E-mail Thread 2/6/08 Subject, HDMA Meeting HSI-MDL-00376363-64 220

Henry Schein
DiBello-20 Industry Compliance Guidelines Healthcare Distribution Guidelines HSI-MDL-00063613-27 225

- - -
E X H I B I T S (Cont'd)
- - -

NO. DESCRIPTION PAGE

Henry Schein
DiBello-21 Interoffice Memorandum, 5/11/09 Subject, Pain Management Clinics Recommendation HSI-MDL-00635472 233

Henry Schein
DiBello-22 Schein SOM Procedural Review 21 CFR 1301.74(b) HSI-MDL-00404369-73 239

Henry Schein
DiBello-23 E-mail Thread 2/10/11 Subject, SOM Procedures HSI-MDL-00007353-55 249

Henry Schein
DiBello-24 Know Your Customer Proposal HSI-MDL-00002682 271

Henry Schein
DiBello-25 US DOJ DEA Letter 6/12/12 HSI-MDL-00065789-90 275

Henry Schein
DiBello-26 E-mail Thread 1/12/12 Subject, California Doctor Linked to Drug Deaths Arrested HSI-MDL-00233032-35 277

- - -

EXHIBITS (Cont'd.)

- - -

NO.	DESCRIPTION	PAGE
Henry Schein DiBello-27	E-mail Thread 1/7/12 Subject, California Doctor Linked to Drug Deaths Arrested HSI-MDL-00115531-34	286
Henry Schein DiBello-28	Individual Opportunity/Issue HSI-MDL-00072607	293
Henry Schein DiBello-29	E-mail Thread 10/1/08 Subject, Doctor Faces Charges on Improper Distribution of Drugs HSI-MDL-00622415-17	297
Henry Schein DiBello-30	E-mail, 11/18/11 Subject, Legal Action & Attached Notice of Hearing HSI-MDL-005912178-86	303
Henry Schein DiBello-31	E-mail Thread 2/1/12 Subject, JDE 629100 Timothy Kowalski HSI-MDL-00020069-70	307

- - -

EXHIBITS (Cont'd.)

- - -

NO.	DESCRIPTION	PAGE
Henry Schein DiBello-32	Letter 11/9/12 From Tejeda to Droz HSI-MDL-00397293-94	313
Henry Schein DiBello-33	Interoffice Memorandum 12/19/12 Subject, Regulatory Assessment of Verifications Computer Systems and Procedures 2013 HSI-MDL-00622252-58	318

- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer

PAGE LINE

None.

Request for Production of Documents

PAGE LINE

None.

Stipulations

PAGE LINE

None.

Questions Marked

PAGE LINE

None.

THE VIDEOGRAPHER: We are now on the record. My name is Henry Marte. I'm a videographer with Golkow Litigation Services.

Today's date is February 19, 2019. And the time is 10:29 a.m.

This videotaped deposition is being held at 200 Vesey Street, New York, New York, in the matter of National Prescription Opiate Litigation.

The deponent today is Michael DiBello.

All appearances are noted on the stenographic record.

Will the court reporter please administer the oath to the witness.

- - -

... MICHAEL DiBELLO, having been first duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. MIGLIORI:

Q. Good morning, sir.

A. Good morning.

Q. My name is Don Migliori. I'm from a firm Motley Rice. I'm going to be asking you some questions today. Throughout the course of the day, I'm going to be handing papers over to you and your counsel asking you questions. Hopefully they're intelligible. If they are not, please stop me. If you don't understand what I'm asking, or if you can't hear me, I'll be glad to rephrase or slow down.

I ask that all your answers be verbal so the court reporter can take down your testimony. I'd also ask that in between my question and your answer, that you give your counsel some time to interpose an objection if necessary.

If you answer -- if you answer my question I'm going to assume that you've understood it. Is that okay

with you?

A. Yes.

Q. And have you gone through this process before?

A. No. I've never been deposed.

Q. Okay. So if at any time you need to take a break, I'm happy to stop, I ask that it be after a full question and answer has been completed, and then we'll take a break. Otherwise we'll take a break about every hour or so. It's my intent to not go very long today.

And I'm hopeful that I can stick to that.

Could you state your full name and your address, please?

A. Michael DiBello, 397 Split Rock Road, Syosset, New York 11791.

Q. Okay. And what is your current job and job title?

A. My current job title is vice president, deputy general counsel, regulatory, at Aceto Corp.

Q. What is Aceto Corp.?

A. Aceto Corp. is a chemical importer distributor of chemicals and pharmaceutical ingredients, nutritional products, industrial chemicals, agricultural protection products.

Q. Does Aceto have any products that are considered controlled substances?

A. Aceto has -- List 1 and controlled substance chemicals.

Q. Do they manufacture control substances or do they just supply chemicals?

A. Aceto does not manufacture any chemicals or ingredients. They only import and distribute.

Q. Okay. And does Aceto have any products that would be related to opiates?

A. No opioid products.

Q. Okay. Before Aceto, what was your employer and your job title?

A. Before Aceto, I worked at

Henry Schein. I was the director of regulatory affairs at Henry Schein, Inc., in Melville, New York.

Q. And what years were you there?

A. I started at Henry Schein in 1996 and I left Schein at 2012.

(Document marked for identification as Exhibit Schein-DiBello-1.)

BY MR. MIGLIORI:

Q. I'm going to show you Exhibit Number 1. It's a copy for you and for your lawyer.

Copy 1 -- Exhibit 1 is simply the notice for today's deposition. You are here pursuant to this deposition.

In preparation for this deposition, did you have any meetings with counsel?

A. Yes.

Q. When were you first notified about this deposition?

A. I was notified about this

deposition about a week or so ago, this particular, yeah.

Q. The day?

A. The day, yeah.

Q. Okay. When is the first time that you actually sat and substantively talked about your testimony, either by phone or in person with counsel?

A. Yesterday. We sat and spoke.

Q. Okay. Was that the first time?

A. We spoke prior to that.

Q. When did you speak prior to that?

A. I would say probably around two or three weeks ago.

Q. Okay. Was that on the phone or in person?

A. On the phone.

Q. Were any documents sent to you to review for today?

A. No.

Q. How long was the phone call a few weeks ago?

A. The phone call was approximately a half hour or so.

Q. And was that with your counsel here today?

A. Yes.

Q. And the next time that you spoke with counsel about this deposition was yesterday?

A. Correct.

Q. And did you meet in person yesterday?

A. Yes.

Q. How long did you meet?

A. We met yesterday, 9:00 a.m. until -- it was around 3:00, maybe 3:15-ish.

Q. Okay. During that time did you review documents?

A. Yes.

Q. Did you review any testimony of other witnesses?

A. No.

Q. Do you recall a gentleman by the name of Shaun Abreu?

A. Yeah. I recall Shaun.

Q. Did you either review testimony that Shaun may have given in this case or did you speak with him about your testimony in this case?

A. No.

Q. How about Mr. Peacock? Have you either reviewed any testimony of Mr. Peacock or discussed his testimony in this case?

A. I have not reviewed any testimony nor discussed any of his testimony.

Q. And other than the documents that counsel brought to you to review, did you have any documents of your own that you brought to counsel?

A. No.

Q. Did you retain any documents after you left Henry Schein in your position relative to your time at Henry Schein? And by documents, I mean

documents that would be dealing with your regulatory responsibilities, particularly in the area of controlled substances.

A. I just want to make sure I understand the question.

Did I --

Q. I can rephrase it if you'd like.

A. Yeah, could you?

Q. Do you have in your possession now, still, since leaving Henry Schein any documents from Henry Schein relative to your roles in regulatory affairs as they relate to controlled substances?

A. I may have. I may have some documents that I --

Q. What kind of documents do you think you have?

A. Documents that I, you know, worked on, were, you know, my documents, work product.

Q. As you know work product is a loaded term. When you say work

product, are you talking about documents related to actual litigation or documents that were maintained in the ordinary course of business?

A. No documents related to litigation. Documents that were maintained in the order -- you know, normal course of business.

Q. And did counsel ask you to bring those documents with you, to the extent that they were related to your job as director of regulatory affairs?

A. No.

Q. Are they in a place that's -- that you -- strike that.

Do you know where the documents are, are you able to gather those documents and produce those, if required by your counsel?

A. I would have to locate them. Yeah.

Q. Okay. Any -- so all the documents you reviewed yesterday for the six hours or so were documents that

counsel brought to you?

A. Correct.

Q. I assume they were things like e-mails and PowerPoint presentations and various documents internal to Henry Schein?

A. Correct.

Q. Were there any external documents, documents from outside the company that you were asked to review to your knowledge?

A. I want to make sure I understand the question. When you say documents outside the company?

Q. Any documents that would be from -- that would have been maintained by somebody other than Henry Schein.

A. Maintained by someone other than Henry Schein or produced by someone other than Henry Schein?

Q. Either. If that's an important distinction.

MR. McDONALD: I'll shortcut this, Don, and represent to you

that every document we showed him had a Henry Schein Bates number from this litigation.

MR. MIGLIORI: Okay. So every -- every document that he saw, you have produced to us?

MR. McDONALD: Correct. If it was from a third party, it was -- it's not like Buzzeo, for example, maintained in Henry Schein files.

MR. MIGLIORI: Right. Or Rannazzisi letters. Anything that --

Mr. McDONALD: Correct.

MR. MIGLIORI: Whatever you showed him, showed up in my production.

MR. McDONALD: Correct.

BY MR. MIGLIORI:

Q. And that's all I'm trying to get it.

Before we get started, whatever it is that you've looked at,

I've had a chance to look at myself?

A. Correct. Yeah, I just wanted to make sure I understood the question.

Q. Sure. And you wouldn't be in a position to answer that, so that was a hard one.

A. Okay.

Q. Okay. Would you say you've never had a deposition taken of you before?

A. No.

Q. All right. I don't have -- do you maintain a current curriculum vitae?

A. No.

(Document marked for identification as Exhibit Schein-DiBello-2.)

BY MR. MIGLIORI:

Q. This is just a snapshot of your -- this is Exhibit Number 2 -- of your LinkedIn page.

A. Okay.

Q. From what I can tell.
A. Okay.
Q. It says, "Michael DiBello, vice president and deputy general counsel at Aceto Corp. and Rising Pharma." This is you, correct?
A. Yes.
Q. And with Aceto, those dates are correct, October 12th, 2012, to present?
A. Correct.
Q. And your office is in Port Washington, New York?
A. Correct.
Q. All right. The period of time that we're going to be talking about today is your time at Henry Schein Inc. It says, "Director of regulatory affairs and regulatory counsel, April 1996 to 2012."
First of all, those are the correct dates of your employment?
A. Correct.
Q. Were you director the entire

time?
A. No.
Q. Okay. What did you hire in as?
A. I hired in as the quality manager.
Q. And what responsibilities did you have as quality manager?
A. My primary responsibility was to develop and implement a quality management system to certify the company to ISO 9000 quality, the international ISO 9000 quality system standard, and to CE Mark their private label products, medical dental products for distribution -- they were already -- you know, selling worldwide.
But in 1996 there were new medical device directives that were being implemented that required the CE Mark certification for distribution into Europe. That was my initial --
Q. Do you recall which -- do you recall which medical devices they

were?
A. I'm sorry?
Q. Which medical devices were they, that you were working on?
A. They were medical devices which included anything from the medical business -- excuse me. I have a sore throat. I apologize.
So, the medical devices included everything in the medical business, which ranged from masks, examination gloves, instruments, to dental devices, again, you know, anything that a dentist would use in their practice. Generally speaking, low risk devices. They didn't make drug-coated stents.
Henry Schein did not make -- again, let me be clear. Henry Schein did not manufacture these devices. They simply had their private label name on them.
Q. Gotcha.
Was that all of your

responsibilities as a quality manager?
A. At that time, that was the -- that was my primary role.
Q. And that started in April of '96. How long did that last, that role?
A. Approximately two years. '96, '90 -- probably into three years.
Q. Sometime in 1999?
A. Yeah. Approximately 1999 my role expanded to include the regulatory function and compliance.
Q. Before we get to that, from 1996 to 1999, did you have any responsibilities whatsoever relative to controlled substances?
A. No.
Q. And during that period of time, did you have any responsibilities relative to regulatory compliance in the area of controlled substances?
A. No.
Q. Did you have any regulatory compliance responsibilities at all in the United States? I know that you had this

European --
A. Right. No.
Q. Before we get to 1999, I want to drop really quickly to Underwriters Laboratories. It lists here from June of 1987 to April of 1996. Almost nine years you were at a company called Underwriters Laboratories?
A. Correct.
Q. And there you were a senior project engineer/lead quality auditor?
A. Correct.
Q. What were your responsibilities there?
A. My responsibilities at UL included quality system audits, to audit and certify manufacturers. And those audits included military standard quality system audits for the government, including independent third-party audits in accordance with the ISO 9000 quality standard, the international ISO 9000 standard.
Q. Same questions, during that

period of time, from 1987 to 1996, did you have any responsibilities whatsoever relative to controlled substances?
A. No.
Q. In that period of time from 1987 to 1996, did you have any responsibilities relative to regulatory compliance, other than the ISO 9000 standards?
A. No.
Q. And your educational background is -- you have a BS in electrical engineering from NYU, correct?
A. At the time it was Polytechnic Institute. They were later merged into -- yeah, it was NYU.
Q. Okay.
A. Now it's all part of NYU, but --
Q. It wasn't NYU at the time?
A. It wasn't NYU at the time. It's now NYU.
Q. Okay. From there you went to UL?

A. Correct.
Q. And then after you left Underwriters Laboratories, there's a two-year gap between 1996 and 1998 that's not accounted for, that I can see on this short bio.
What did you do in those two years?
MR. McDONALD: I'm sorry, where -- where are you looking at, Don? I don't see a gap.
MR. MIGLIORI: I'm sorry.
BY MR. MIGLIORI:
Q. I see that you left Underwriters in April of 1996 and you started law school in 1998. And I'm just asking you what happened between those two years.
MR. McDONALD: Okay. But his -- he shows that he is at Henry Schein in 1996.
MR. MIGLIORI: Okay.
THE WITNESS: I was working at Henry Schein.

BY MR. MIGLIORI:
Q. Okay. So you got your law degree while you were at Henry Schein?
A. Correct.
Q. All right.
A. 1998 I went to Touro.
Q. Okay. So you went right from UL to Henry Schein. And then after two years, while you were still a quality manager at Henry Schein, that's when you started law school at Touro, correct?
A. Correct.
Q. Was that a part-time law school?
A. Correct.
Q. And you got your law degree in 2002?
A. Correct.
Q. And then it says, "Columbia Business School, Certificate in Business Excellence." What is that program, in 2008 to 2011?
A. That's a mini executive MBA program where you take X number of

Page 34

classes and courses. I think it's 24 credits over a period of time, two years or so. And you get a certificate from Columbia Business School for their -- this mini MBA program.

Q. Okay.

A. Executive -- they call it executive MBA program.

Q. You don't actually receive a masters in business administration, do you?

A. No. It's not a masters. It's a mini MBA program.

Q. Okay.

A. Executive MBA program, they call it, for executives.

Q. And is that the one that's actually in the business school, or is that one that's part of the journalism school?

A. I'm not familiar with the journalism school.

Q. Okay.

A. I think it's the business

Page 35

school.

Q. Okay. And you got a certificate in 2011 there, while you -- again you were still at Henry Schein?

A. Correct.

Q. And that I assume was part-time or evenings or something like that?

A. It was not evenings. It was -- they had credits that -- courses that were either two, three, four or week-long courses that you took during that period.

Q. Okay. And what did you study in particular in that business school?

A. There were courses on negotiation. There were courses on leadership. There were courses on management, communication, strategic leadership.

Q. Okay. So either -- in any of your educational experience, did you take any courses specific to regulatory

Page 36

affairs? Did you have any training whatsoever in regulatory affairs in your -- in your courses?

A. No.

Q. At Underwriters Laboratories, you had no experience or background in domestic regulatory affairs, correct?

A. Not domestic regulatory affairs.

Q. And by domestic, I mean the United States.

A. Correct.

Q. And for the first three years at Henry Schein from 1996 to 1999, you had no roles relative to regulatory affairs in the United States on any issue including on issues relating to controlled substances, correct?

A. Correct.

Q. All right. So we'll get back up to Henry Schein. So in 1999 your job title changed from quality manager to what?

Page 37

A. I believe it was director of quality or QA.

Q. Tell me how your responsibilities changed in that role.

A. The change was due to a promotion from manager to director level. And the -- the role basically changed in that it expanded from corporate quality management system certification to rolling out the ISO certification to Henry Schein's distribution centers.

Q. The ISO responsibilities up until this point had been for the international market, correct?

A. Correct.

Q. Did that change to domestic when you got this promotion?

A. Well, it -- the international certification relied on the domestic certification of Henry Schein corporate office.

What changed was the certification of the distribution centers. So the expansion of ISO 9000

now became not just a corporate certification for the European market, but implementing a quality management system for Henry Schein's distribution centers.

Q. At this point in 1999, are you now -- in dealing with the distribution centers, are you now responsible for any issues relating to controlled substances?

A. 1999, no. I don't -- I don't believe so.

Q. Did you have any responsibilities relative to suspicious order monitoring systems or standard operating procedures, relative to controlled substances?

A. I don't believe so, not in 1999.

Q. How long did you hold that job as director of quality assurance?

A. I don't recall when my -- the exact time when -- when I was promoted to director of regulatory

affairs. But probably within a few years after that.

Q. Okay.

(Document marked for identification as Exhibit Schein-DiBello-3.)

BY MR. MIGLIORI:

Q. Let me show you Exhibit Number 3.

[redacted]

[redacted]

[redacted]

A. Who is L. David?

Q. Yes.

A. That was my immediate supervisor, Len David.

Q. Okay. And was he your supervisor the entire time that you were at Schein?

A. No.

Q. When did he become your supervisor?

A. I don't recall the specific time. I don't remember exactly when.

Q. Okay. So sometime between 1999 and 2007 you took on a role with regulatory affairs, correct?
A. Correct.
Q. Whenever that was, between those two dates, is that when Len David became your supervisor?
A. Correct.
Q. All right. And up until that point, you had no background in regulatory affairs, at least as it related to controlled substances, correct?
A. Correct.
Q. When you became a director of regulatory affairs, did you take on any training relative to issues concerning controlled substances?
A. Yes.
Q. When was that and what was the training?
A. The training was ongoing. We always attended seminars, conferences, regardless of whether it was controlled

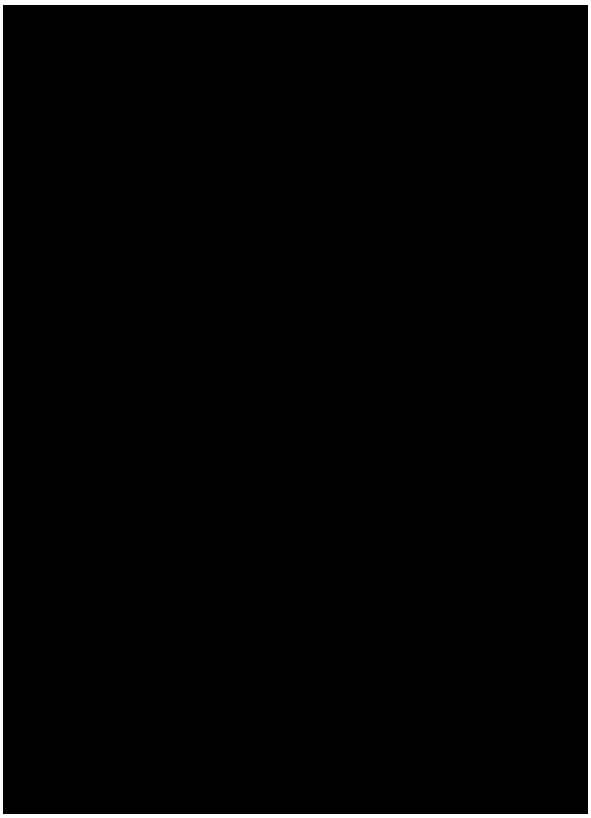
substances, hazardous materials, FDA, DEA. It was ongoing training all the time throughout my entire tenure.
The training consisted of conferences, seminars at trade associations, Food and Drug Law Institute, and general -- general training at, you know, it could be at a law firm, as well, for CLE credits. So it was all of the above, and again throughout my entire tenure.
Q. Fair to say --
A. There was no formal, you know, if you're looking for a formal college accredited curriculum, there was no formal college accredited program, per se.
Q. Is it fair to say that your training in regulatory affairs was on-the-job training?
A. It also included on-the-job training.
Q. Okay. In addition to the conferences and the trade association and

the seminars?
A. Correct. That's correct.
Q. And by trade associations, did you attend HDMA conferences?
A. That's correct.
Q. All right. Any other trade associations that you can recall that you learned or were trained in the area of regulatory affairs?
A. Another trade association was the Health Industry Distribution -- HIDA, Health Industry Distribution Association. I was also a member of the Food and Drug Law Institute. I was also a member of the New York State Bar Association, food and drug law group, which also had conferences and seminars.
Q. Okay. Any of the documents that you think you have in your own possession, are any of those related to any of these conferences, seminars, didactic training sessions?
A. You mean like --
Q. Manuals, CLE handouts?

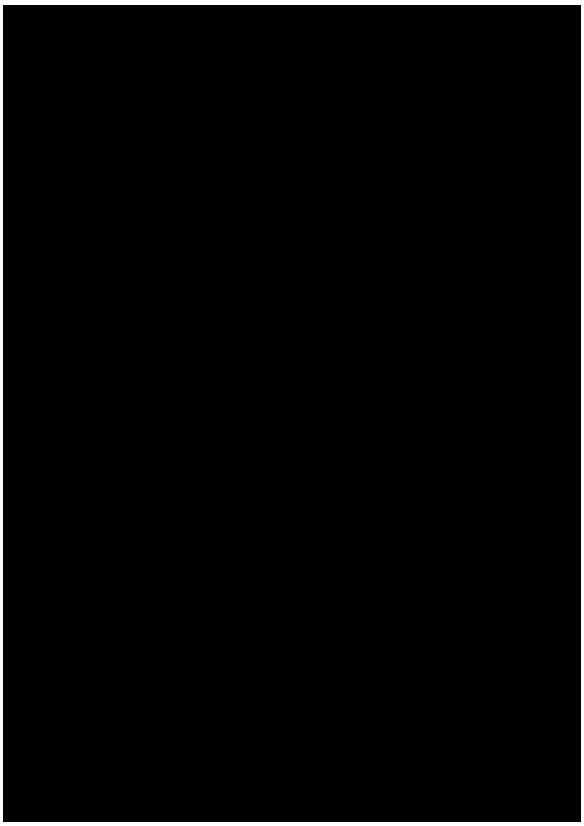
A. I probably do not have any of those anymore just by virtue of the fact that they would be outdated.
Q. I don't keep mine either. Just curious.

[redacted]

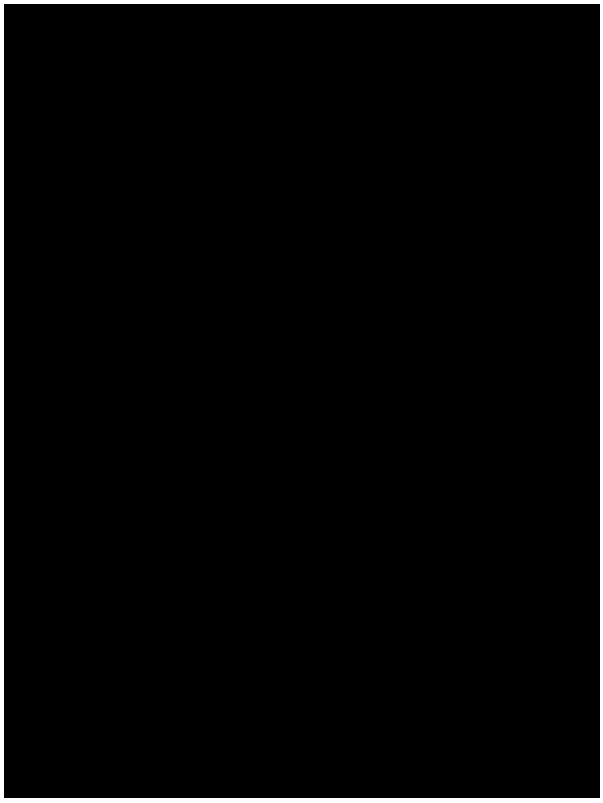
Page 46



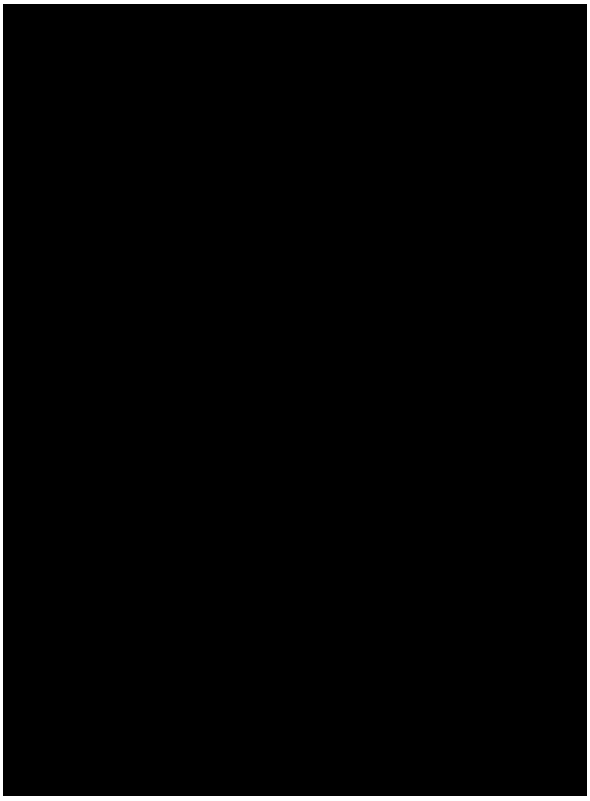
Page 48



Page 47



Page 49



Q. And the distinction I think you're making, I'm asking, is that there were some compliance responsibilities outside of your group in regulatory affairs, correct?

A. There were some compliance activities outside the regulatory department.

Q. And if I'm mischaracterizing this, please correct me, but there were some front line responsibilities within the verifications department that were

separate and distinct from the roles within regulatory affairs, correct?

A. Correct.

Q. As the orders and the initial pends, and by pends, P-E-N-D-S, I'm -- I'm referring to anything that's triggering a potential for suspicious order. All of those were handled on the front line by the verifications department, correct?

A. Please restate the question.

Q. Sure.

The orders as they came in to Henry Schein for controlled substances particularly, I'm talking about Schedule II opioids, came first through the verifications department for purposes of detection or potential detection of suspicious orders. Is that a fair statement?

A. That's correct.

Q. Regulatory affairs only got involved with pended or suspicious orders if they escalated through the -- the

verifications department, correct?

A. Correct.

Q. And during the period of time that we are talking about here in 2007, was it Shaun Abreu that was primarily responsible for verifications, do you recall?

A. I don't recall when Shaun became the primary person. It may have been 2007, but I don't remember that.

Q. But -- but in any event, there was a -- there was a verifications layer for suspicious order monitoring that existed separate and distinct from regulatory affairs?

A. That's correct.

Q. And whether something escalated from verifications to regulatory affairs, was a decision made -- at this time in 2007, was a decision made by the verifications department, correct?

A. Correct.

Q. That is, there was no

electronic monitoring at this stage of orders such that there would be an automatic report of anything suspicious to your department, correct?

MR. McDONALD: Object to the form.

THE WITNESS: Electronic monitoring that would -- I'm not sure I follow the question.

BY MR. MIGLIORI:

Q. That's fine. If you don't understand, that's fine.

A. Yeah.

Q. So we'll go through sort of the history of -- of the suspicious order monitoring program.

But let me ask you more basically. When did you first get involved yourself with any responsibilities as it related to suspicious order monitoring programs at Henry Schein?

A. I don't recall the time period when I first initially got

involved with suspicious order monitoring.

Q. Was it a component part of your responsibility when you became -- when you moved into regulatory affairs? Was it immediately part of your responsibility or oversight?

A. When I moved into regulatory affairs it would have become part of my responsibilities.

Q. Okay.

A. That's correct.

Q. But as you sit here today, you don't recall exactly when that was?

A. I don't recall the exact time period.

Q. We know it's some time before this 2007 flowchart, right?

A. Yes.

Q. I'm not going to have you go through this right now. But I'm going to mark it and I may go through it at a break.

(Document marked for

identification as Exhibit Schein-DiBello-4.)

BY MR. MIGLIORI:

[redacted]

[redacted]

[redacted]

Page 58

[redacted]

Page 59

[redacted]

Page 60

[redacted]

Q. Okay. In preparation for today, did you do anything to review the activity of Henry Schein relative to the county in which claims have been brought in this litigation; that is, Summit County, Ohio?

A. No.

Q. You're familiar with the obligations of Henry Schein to report to the ARCOS data over time, correct?

A. Correct.

Q. And that came under your department; that is, what -- let me restate that.

Did ARCOS reporting, was that a responsibility of regulatory affairs or verifications?

A. ARCOS reporting was the responsibility of verifications.

Q. Okay. So that was not part of your responsibility?

A. Nope.

Q. Suspicious order monitoring, was that regulatory affairs, verifications or both?

A. Suspicious order monitoring was primarily a responsibility of verification.

Q. Okay. What role, if any, did regulatory affairs play in that suspicious order monitoring program at Henry Schein while you were there?

A. Regulatory was involved in

Page 61

Page 62

the engagement of Buzzeo to develop an enhanced suspicious order monitoring process, and to implement, to help coordinate and implement and facilitate those enhancements to our suspicious order monitoring process.

Q. Okay. So just briefly, if you will, what is Buzzeo and how did you interact with Buzzeo at the beginning?

A. Buzzeo is a consultant that Henry Schein used prior to my joining the company.

He was consulting, I would say, several years prior to joining -- prior to my joining the company.

Buzzeo was a former DEA agent. And we retained Buzzeo to help us with the DEA project and on occasion, you know, I mean, he did -- he did a lot. He did audits for us. He advised us in several different aspects with respect to DEA.

Q. So when you first got involved with regulatory affairs sometime

Page 63

before 2007, Buzzeo had already been consulting with Henry Schein --

A. That's correct.

Q. -- for suspicious order monitoring?

A. He was consulting with Henry Schein way before I took over regulatory.

Q. Okay.

MR. McDONALD: So let me -- let me tell you, just be sure he's done with his question before you are answering. You're doing pretty good. The last one you answered it halfway through his question.

THE WITNESS: Okay. Sorry.

MR. McDONALD: Just wait until he's done. He'll pause occasionally. He's trying to throw you off.

MR. MIGLIORI: I'll try to talk quicker so we can get to your answer quicker.

THE WITNESS: Okay. I

Page 64

thought you -- I thought you stopped.

MR. MIGLIORI: No, no, that's fine. That's going to happen. The more we talk conversationally, the more that happens.

THE WITNESS: Sure.

MR. MIGLIORI: Sometimes it takes somebody outside watching us to point it out to both of us.

THE WITNESS: Sure.

(Document marked for identification as Exhibit Schein-DiBello-5.)

BY MR. MIGLIORI:

Q. Let me show you Exhibit Number 5. This is a PowerPoint presentation that bears your name on the cover.

A. Yes.

Q. I'll tell you that from metadata, we're able to decipher that the date of this is November 2, 2009. Okay?

Page 65

A. Okay.

Q. Let me just show you. So Cegedim Dendrite you understand to be an iteration of Buzzeo?

A. That's correct.

Q. All right. So this is a presentation that bears your name. Do you recall putting this together?

A. Yes.

Q. Did you review this in preparation for today?

A. Yes.

Q. And so, when you're talking about Buzzeo and the consulting, we're talking about the same group here, correct, that you -- that you seem to have presented this presentation with, right? It's their watermark or their -- correct?

A. Correct.

Q. Do you recall giving this presentation, actually presenting it?

A. Yes.

Q. And what -- what was your

audience? Who was your audience, the annual controlled substances conference?

A. So the audience -- Ron Buzzeo did conferences and seminars, as we discussed earlier. That was one of the training programs that we attended.

He gave annual -- at least once a year, sometimes twice, so the audience was distributors, manufacturers.

Q. This would have been your competitors in the market?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. Right? Other distributors?

A. Yes.

Q. So you're presenting at this conference with other distributors Henry Schein's approach to DEA compliance. Is that a fair generalization?

A. Yes.

Q. Okay. These were the topics. You gave a quick overview of the company.

Is this -- was this accurate at the time, that Henry Schein was the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets?

A. Yes.

Q. And that includes, obviously, controlled substances?

A. Yes.

Q. Customers include dental practices and laboratories, physician practices, and animal health clinics, as well as government and other institutions. Those were your clients?

A. Correct.

Q. Over 12,000 employees at the time. Business in 23 countries. And over $6 billion in sales. That was the size of the company?

A. Correct.

Q. The next slide you put here basically sets forth sort of the foundation of DEA compliance as it

relates to controlled substances, correct?

A. Correct.

Q. This is the excerpt from the Controlled Substances Act that puts on the distributor the responsibility of designing and operating a system to disclose to the registrant suspicious orders of controlled substances, correct?

A. Correct.

Q. You wrote that "the regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system." So you were aware of the obligation of DEA -- DEA registrants like Henry Schein in their sole responsibility to design and operate suspicious order monitoring programs for their company?

A. Can you repeat the question?

Q. Sure. That statement, the -- "The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such

a" -- "such a system."

That statement refers to Henry Schein, correct?

A. Correct.

Q. That is, designing and operating a system for Henry Schein suspicious order monitoring system was non-delegable. It was something that you had to do yourself, right?

A. That's correct.

Q. In reference to the December 2007 letter from DEA, are you familiar with what's referred to as the "dear registrant" letters or the Rannazzisi letters? Do you recall reading those?

A. Vaguely. In 2007.

Q. So the citation here to the December 2007 letter. Do you have a specific recollection of -- of having read that at the time, or been aware of it at the time?

A. I have a general recollection.

Q. Okay. And this excerpt here, this is something that you pulled out from that letter for the purposes of this presentation to the trade association, correct, or you had it pulled?

A. I had it pulled out, yeah. I didn't prepare it.

Q. And then you go through some challenges that you felt. You thought this was an unclear requirement with respect to knowing your customer.

What -- what do you recall, if anything, was unclear about the obligations under the Controlled Substances Act to know your customer, if you can recall?

A. Do I recall what -- can you repeat that question?

Q. Yeah. Your first bullet point here says, "Unclear requirements with lack of guidance. Know your customer."

Do you recall why you put

that bullet point, that there was -- there were unclear requirements with lack of guidance relative to "know your customer" obligation?

A. Okay. So the way the statute is written, it was not specific for a particular customer to determine whether an order could be, you know, deemed suspicious. And that was the -- so it was not specific. It was -- it was a very broad, very general requirement.

Q. Do you recall in any of the letters received in 2007 or 2006 a guidance from the DEA about what are some of the things that are deemed to be red flags or anomalies that need to be investigated for the "know your customer" obligations?

A. I recall that they -- there was a -- you know, in the letter there was some guidance offered.

Q. Okay. And again the date of this is November of 2009. By this point you said you were a member of the HDMA.

Do you recall the guidance provided to Henry Schein and other distributors from the HDMA about the "know your customer" obligations, specifically in 2008?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. Do you recall that, that's my only question.

A. Not specifically, but --

[redacted]

Q. Okay. We'll get into the specifics of the process. But I want to direct your attention to Page 11 right now, just for a timeline.

A. Okay.

Q. This is your PowerPoint. So

I just want to sort of go through. Do you recall looking at this timeline in preparation for today?

A. Yes.

Q. All right. So in this slide that you prepared for this presentation, you have that the suspicious order monitoring project started in September of 2007. Is that the beginning of the implementation of the Buzzeo recommendations?

A. No.

Q. What is that date?

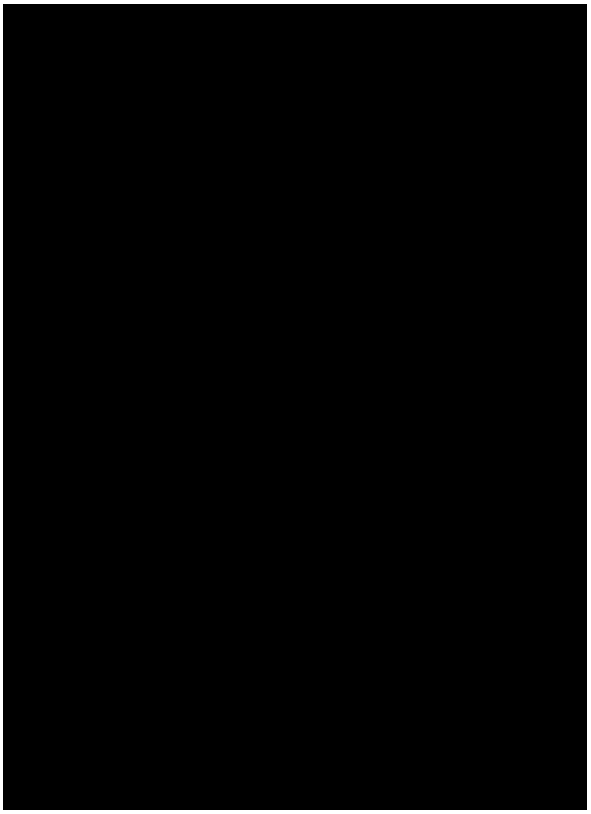
A. I'm not -- I'm not -- I'm not recalling what that date signifies.

Q. Shaun Abreu testified in this case as the person designated by Henry Schein to speak for the company relative to the suspicious order monitoring program in place. To the extent that his -- that he has a recollection of this and -- and what it signifies, at least at this stage, given your -- your current memory, would you

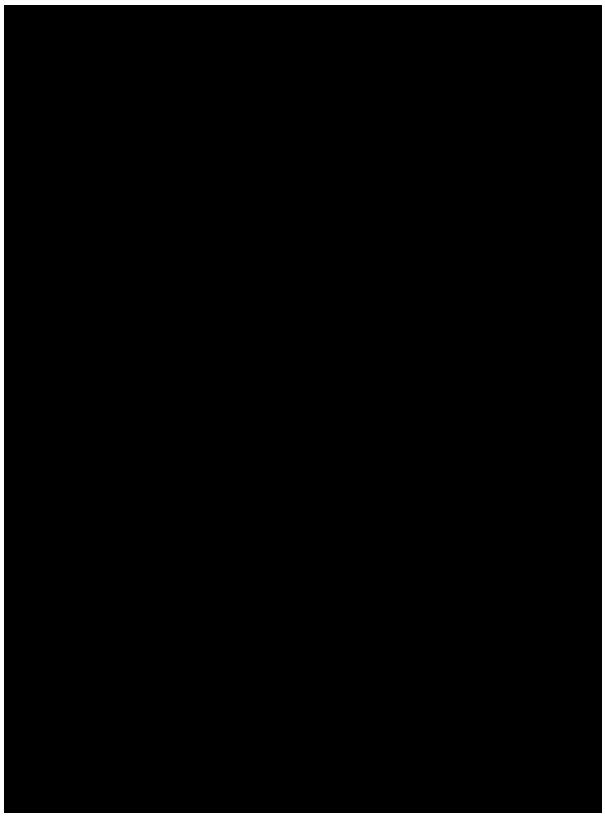
defer to his testimony, his memory?
MR. McDONALD: Object to the form.
THE WITNESS: Would I -- I just want to make sure I understand the question.
Would I defer to his recollection?
BY MR. MIGLIORI:
Q. He's testified and was designated by Henry Schein as the person who will speak for the company, not just for himself --
A. Okay.
Q. -- on what these dates signify. You have not reviewed that testimony, have you?
A. No.
Q. All right. And as you sit here today, you personally don't have any information about what the suspicious order monitoring project start date means, is that fair to say?
A. Correct. I don't.

Q. This is your slide, but you just don't recall as you sit here today?
A. I don't recall what that project start date means.
Q. Okay. In November of 2007, in your slide, it says, "Restrictions set up to prevent accounts from ordering products not normally used in their practice."
Do you recall a recommendation of Buzzeo or Dendrite, whatever the name was at the time, that there be an immediate standard operating procedure to prevent certain accounts from getting products based on practice type?
A. I don't recall that specific recommendation.
Q. Okay. But you put this in your slide presumably because there was a decision in November of 2007 to put in an immediate restriction on certain accounts, correct?
A. Well, I would -- you said

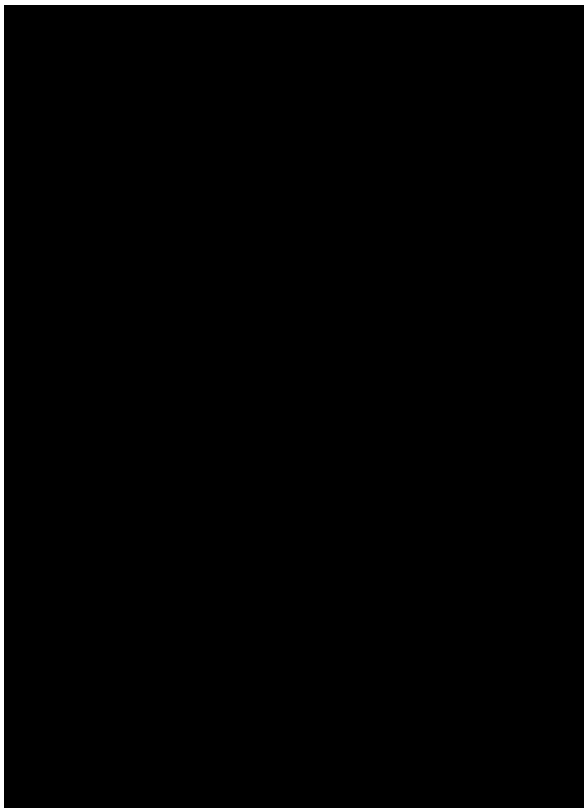
immediate. It was -- it was -- it says here, "Restrictions set up to prevent accounts from ordering products not normally used in their practice." So that's -- that was implemented. I would -- I would agree that it was implemented as stated here on the slide.
MR. McDONALD: You okay?
THE WITNESS: It just went down the wrong pipe.
(Document marked for identification as Exhibit Schein-DiBello-6.)
BY MR. MIGLIORI:



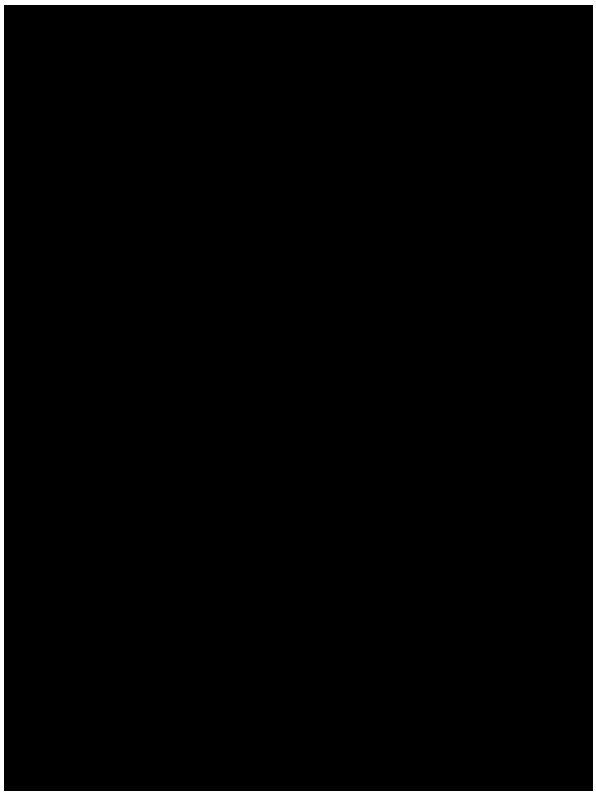
Page 78



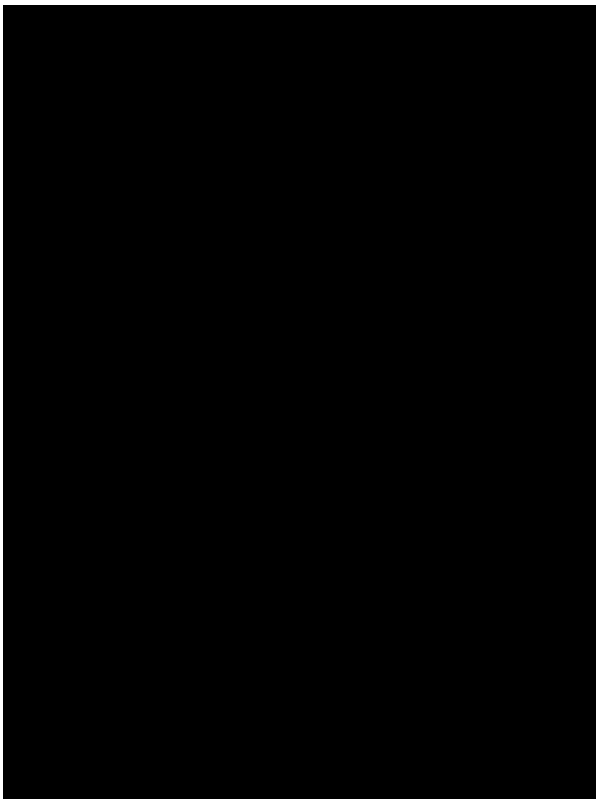
Page 80



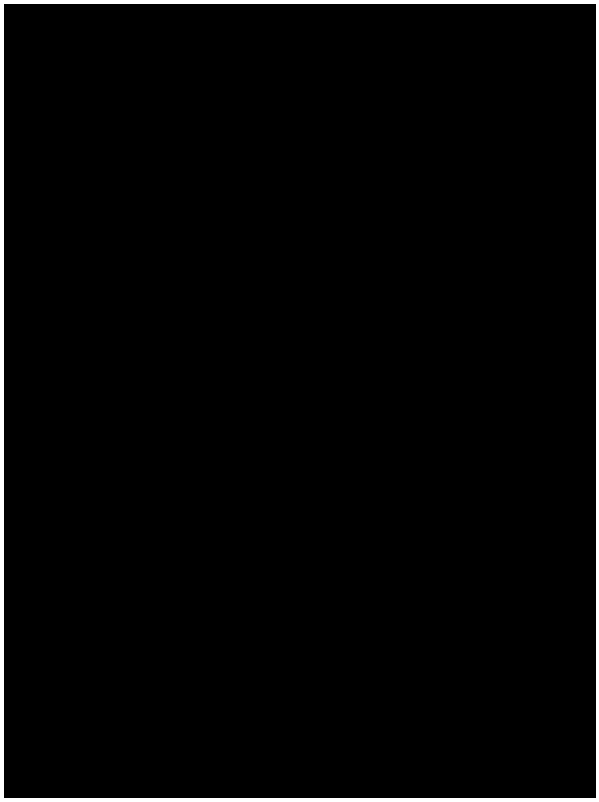
Page 79



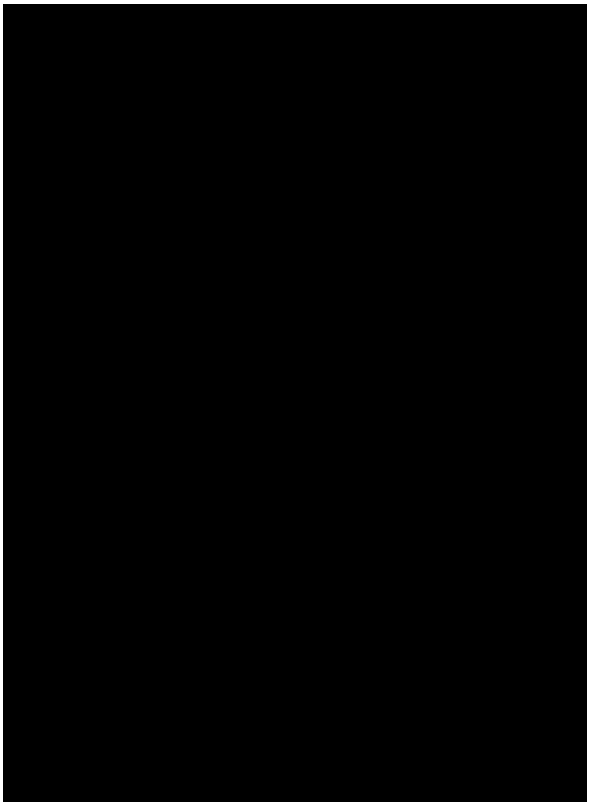
Page 81



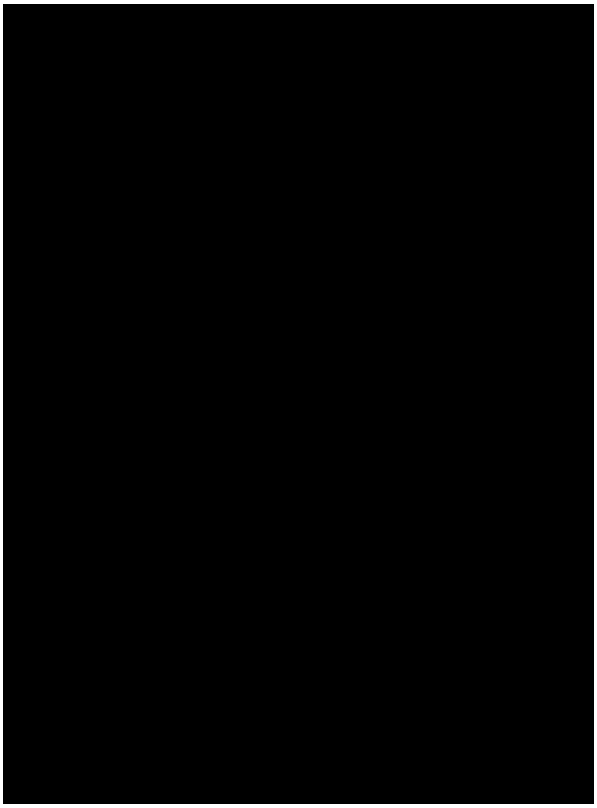
Page 82



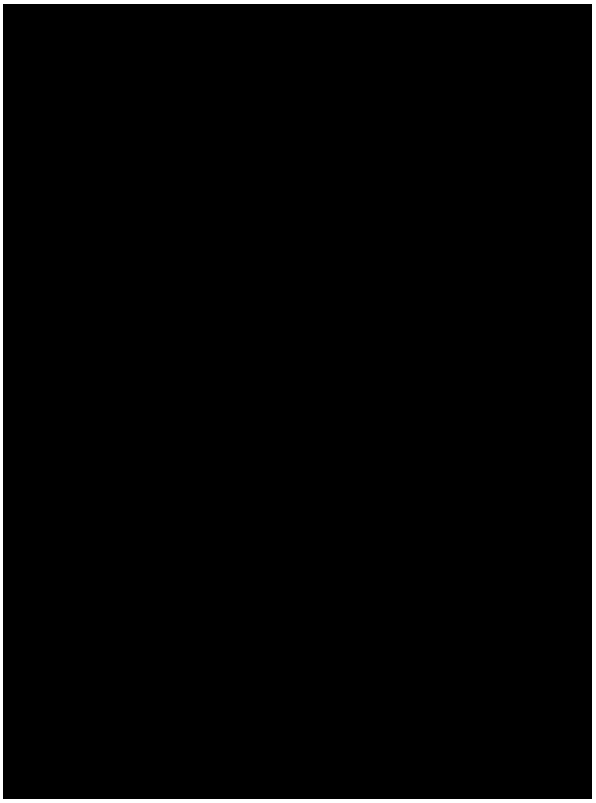
Page 84

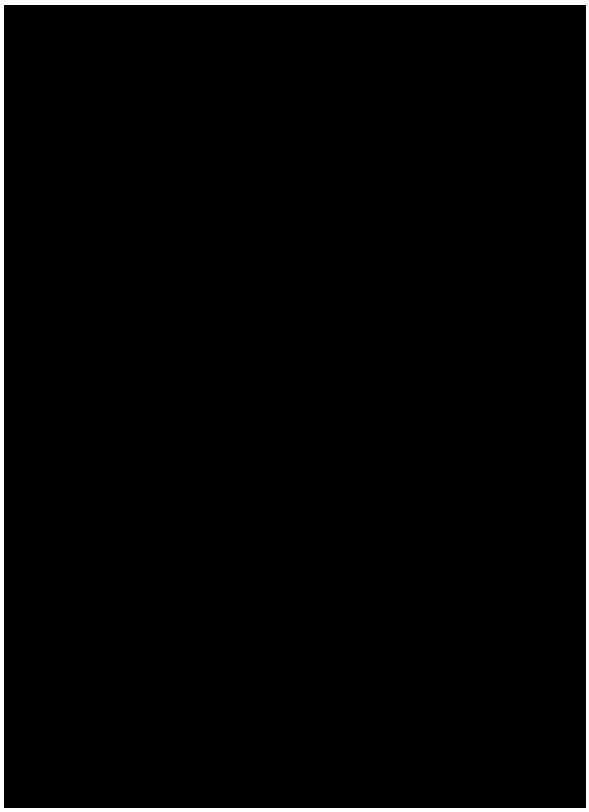


Page 83



Page 85





A. That's correct.
Q. All right. And before we take a break, just to get this out of the way.
You didn't have any responsibilities or interactions with Henry Schein after you left the company, did you?
A. That's correct.
Q. I saw that you offered to help in the transition, but once you left the company, you lost -- or you no longer maintained any communications, contact, or interactions with either Henry Schein or Buzzeo with respect to Henry Schein's suspicious order monitoring program, correct?
A. That's correct.
MR. MIGLIORI: Why don't we take a break.

THE VIDEOGRAPHER: All right. Stand by, please. Remove your microphones. Okay. The time is 11:49 a.m. Going off the record.
(Short break.)
THE VIDEOGRAPHER: Okay. We are back on the record. The time is 12:06 p.m.
BY MR. MIGLIORI:
Q. I want to try to fill in some of that timeline now with some specifics and some experience directly.
Let's start at the beginning.
So sometime in early 2000s when you first got to regulatory affairs, did you -- did you get there as director, did you go right into a director position?
A. When I got to regulatory affairs?
Q. Yes.
A. Yeah. I was director of

quality.
Q. Right.
A. And then I believe the title was changed to director of regulatory affairs.
Q. Okay. And that's what happened some time between --
A. 1999.
Q. -- 1999 and 2007?
A. Yeah. Yeah.
Q. And it's when you became director of regulatory affairs that you first started to deal with the Controlled Substances Act and the obligations relative to DEA compliance, correct?
A. Correct.
(Document marked for identification as Exhibit Schein-DiBello-7 and Schein-DiBello-8.)
BY MR. MIGLIORI:
Q. This is Exhibit 7. It's just a statement of the Controlled Substances Act. Do you recognize that as

Page 90

the part of the Controlled Substance Act that governs the distributor's responsibility as it relates to designing and operating a system to disclose to the registrant suspicious orders of controlled substances?

A. Correct.

Q. It talks about informing the DEA in the area of suspicious orders when discovered by the registrant. You understood that to be an obligation under -- an obligation of Henry Schein to report suspicious orders when discovered?

A. Correct.

Q. And you see that this act was enacted in 1971?

A. Correct.

Q. So I assume for all relevant time that you were at Henry Schein, that you understood and appreciated this was the obligation, correct?

A. Correct.

Q. You also understood as the director of regulatory affairs that under

Page 91

the Act, "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," that that was the definition in part of suspicious orders?

A. Correct.

Q. As director of regulatory affairs at Henry Schein, you also appreciated that under that same act, Congress made certain findings about controlled substances? Were you aware that there were certain findings, congressional findings about controlled substances?

A. I don't recall the specific findings.

Q. Did you appreciate, while you were director of regulatory affairs at Henry Schein, that, "The illegal importation, manufacture, distribution and possession and improper use of controlled substances have a substantial and detrimental effect on the health and

Page 92

general welfare of the American people"? Were you aware of that?

A. Yes.

Q. And were you aware that in the scheduling of drugs, going back to 1970, that the Schedule II drugs were defined as, "A, the drug or other substance has a high potential for abuse"? Did you appreciate that as director of regulatory affairs?

A. Yes.

Q. Did you appreciate as director of regulatory affairs that a Schedule II drug was, "A drug or other substance, has a currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions"?

A. Correct.

Q. Did you appreciate as director of regulatory affairs at Henry Schein that Schedule II drugs -- that, "Abuse of the drug or other substance may lead to severe psychological or physical

Page 93

dependence"?

A. Yes.

Q. And did you appreciate while you were director of regulatory affairs at Henry Schein that opioids were Schedule II drugs?

A. Yes.

Q. At some period of time, hydrocodone was a Schedule III drug -- actually, were you aware of the fact that hydrocodone was a Schedule III drug during the time that you were director of regulatory affairs at Henry Schein?

A. I don't recall.

Q. I was going to go through some documents chronologically that have your name.

(Document marked for identification as Exhibit Schein-DiBello-9.)

MR. MIGLIORI: The first one is Exhibit 9.

BY MR. MIGLIORI:

Q. Now when you first got to

Page 94

regulatory affairs, what did you understand the suspicious order monitoring program to be?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. Before we get to the document, what was in place at the time that you started for controlled substances?

A. When I started as director of regulatory?

Q. Yeah.

A. My recollection is that there was a suspicious order monitoring system in place to ensure that we detected suspicious orders and reported them accordingly.

Q. That system in place was a system that was day-to-day managed by the verifications department?

A. Verification department had a primary responsibility for that.

Q. Okay. And when you first

Page 95

got there, do you recall who was responsible for verifications at the time?

A. I don't recall who was responsible for verification at that time.

Q. What, if any, responsibilities did your department have relative to the suspicious order monitoring program in place when you became director of regulatory affairs?

A. My team would get involved when they had questions that the verifications group were not sure how to handle.

Q. Did regulatory affairs set any thresholds at that time when you first started as director?

A. No.

Q. Did regulatory affairs establish any definitions of what is a suspicious order?

A. No.

Q. Did regulatory affairs

Page 96

establish any definitions of what is a pended order?

A. No. When I -- when I took over the group --

Q. At the beginning.

A. At the beginning, no.

Q. And did regulatory affairs have any responsibilities with respect to the due diligence performed when onboarding a new customer at the time that you started?

A. At the time that I took over, no.

Q. Did regulatory affairs have any responsibilities with respect to "know your customer" obligations of an existing customer of Henry Schein when you took over as director?

A. I don't recall.

Q. Is it fair to say that relative to the suspicious order monitoring program that existed when you took over as director of regulatory affairs, that your department was there

Page 97

as a resource to verifications when they chose to use it?

A. Yes.

Q. Otherwise, the suspicious order monitoring program, to the extent it existed when you started as director, was managed, implemented, audited by the verifications team?

A. There's several parts to that question, all right. So managed by the verification team, that's -- that was their primary responsibility.

Implemented, yeah, I guess they would implement their, you know, procedures and practices.

Audited by the verification team, I don't recall.

Q. Okay. You've had a recollection that Buzzeo was already in place as a consultant for the suspicious order monitoring program at the time that you took over as director, is that -- do I remember that correctly?

A. So Buzzeo was a consultant,

Page 98

for all things DEA, when I took over.
Q. Okay.
A. Including the SOM.
Q. Okay. So were you aware of any audits at the time that you took over as director that were being performed by your department of the suspicious order monitoring program?
A. Audits? I don't recall audits.
Q. Do you recall whether Buzzeo had already or were in the process of doing any audits of the suspicious order monitoring program when you became director?
A. I don't recall.
Q. As you sit here today, is your first recollection of a change in the existing suspicious order monitoring program that you inherited when you became director, the first change of that was the change that we saw in the timeline, that is, at the end of 2007, beginning of 2008?

Page 99

A. The first change?
Q. The first change in the suspicious order monitoring program, yes.
A. 2007 being the first change, is that the question?
Q. No. Let me repeat it.
You became director sometime before 2007.
A. Yes.
Q. I assume we are talking about a matter of two, three, or four years.
A. I would say probably more than that. I would say closer to 2000, 2001, '2. The early 2000s --
Q. Okay.
A. -- when I became --
Q. From 2002 until 2007 when you first -- the first date you put on the SOM project in the timeline we discussed there --
A. Okay.
Q. -- were there changes made to the suspicious order -- suspicious

Page 100

order monitoring program at Henry Schein that you can recall?
A. I can -- I can't recall specific changes. But I recall that it was a -- it was an ongoing evolutionary process.
Q. Okay. And was that evolutionary process being managed by regulatory affairs or by the verifications department?
A. It was a collaborative effort --
Q. Okay.
A. -- where both teams worked to continuously, you know, review and monitor the -- the process.
Q. And what role did you play, if any, in that process?
A. My role as the director was to provide the resources and support for the verifications team, to make sure that Sergio and his team, the regulatory team, would be able to support the verifications group.

Page 101

Q. And do you recall any ways in which Sergio and his team supported the verifications group in the time frame from 2002 to 2007 specifically to change the system? Do you recall anything specifically?
A. I don't recall anything specifically. But I know that there -- there are a lot of meetings, and a lot of interaction and a lot of discussion about the suspicious orders monitoring system.
Q. Did you participate in those discussions?
A. Yes.
Q. Were there regular meetings in that time frame?
A. There were meetings. There were -- there were lots of meetings with the verifications group and the IT group.
Q. Okay. And when did -- when did the -- did you -- strike that.
In those meetings, was it the verifications department that was -- that was relying on Sergio Tejeda's team

Page 102

for regulatory support?
During that period of time was it the verifications team that was operationally implementing the system?
MR. McDONALD: Object to the form.
THE WITNESS: During that time was the verification team implementing the system, the suspicious order monitoring system?
BY MR. MIGLIORI:
Q. Yeah.
A. Yes. They -- they -- the verifications team implemented the system. It was -- yeah.
Q. What resources or support would Sergio Tejeda be giving to them in that time frame?
A. The support would be regulatory technical support in the form of helping them to decide, for example, if this order was suspicious or not.
If this -- you know, at some

Page 103

point in time, there was a lot of activity and support with the consultant, Buzzeo. So that's another form of support between Sergio and the verification team.
Q. Was it the regulatory affairs department that retained Buzzeo, that chose to retain Buzzeo?
A. The regulatory team was the primary interface with -- with Buzzeo and made the decision to -- to retain Buzzeo.
Q. Other than what we saw today, which referenced 2007-2008 as the suspicious order monitoring program designed in conjunction with Buzzeo, are you aware of any other Buzzeo changes to the suspicious order monitoring program prior to 2007?
A. I'm not aware of specific changes, but I recall that the -- the Buzzeo engagement occurred before 2007. And again, I would -- I would -- you know, I would call Buzzeo, Sergio would call Buzzeo any time there was a

Page 104

question. So there was -- there was -- again, you know, we had a constant interaction with him on a regular -- not a regular, you know, daily basis, but on an occasional basis when we had a question about a DEA issue or a suspicious order monitoring -- suspicious order.
Q. Okay. Let me show you Exhibit 9 that I've already given you. This is an e-mail that was copied to you. When you deal with -- deal with e-mails, you start at the bottom and go up.
A. Okay.
Q. That's the way the chains work.
But this is January of 2007. And it's from Donna Remondino to you and others. At that time what did Donna Remondino do?
A. Donna worked in the verifications group.
Q. She wrote to you and said, "Trib called."

Page 105

Who is Trib?
A. Trib is a programmer, he worked in IT.
Q. Okay.
A. He's a IT programmer.
Q. "Trib called to inform me that they will be purging the control drug files and we will only have access to five years of history. I wanted to make sure prior to this being done that the DEA and state does not require longer history on file. I know we get requests to pull information longer than five years, but I am not sure what is our requirement. Trib will wait to do the purge on regulatory findings. Thank you for your help."
Do you recall her reaching out to you for this issue?
A. I don't recall the specific issue. Again, there were -- there were lots of questions between the verification and -- and the regulatory group.

Q. Is this one of the ways in which verifications used regulatory affairs as a resource?
A. Yes, yes.
Q. In response to that, Sergio Tejeda, who at this point in January of '07 was reporting to you, correct?
A. Correct.
Q. Sergio responded copying you, saying, "Donna, purging drug files older than five years is acceptable and in compliance with DEA regulations and company policy. For future reference on recordkeeping for controlled substances products, I'm attaching a copy of the corporate record retention policy. Please ensure we maintain controlled substances records accordingly."
Do you recall that that was the policy at Henry Schein, to keep controlled substance drug files for five years only?
A. I don't recall specifically the five-year policy. But I know we had

a policy.
Q. Do you know why -- do you know why Henry Schein maintained a five-year policy, purpose behind it?
A. Do I know why Henry Schein maintained a policy?
Q. A five-year --
A. Five-year --
Q. -- record retention policy.
A. No, I don't. I don't know why it was five years.
Q. We've talked a lot in other depositions about the -- the databases and the computer systems. At this time, is the JD Edwards, is that the name of the system?
A. JD Edwards.
Q. Was that in place?
A. Yeah, I think that was the name of the system. Sounds right.
Q. Did regulatory have any responsibilities with respect to setting the record retention policy or decisions to purge records?

A. The record retention policy was set by legal.
Q. That's -- is regulatory part of legal or is that a separate department completely?
A. At what point in time are you referring to?
Q. Let's start with 2007.
A. In 2007, I don't recall the exact date, but I believe at that time period, regulatory was part of legal. There was a point that regulatory was not part of legal. So there -- there was a transition. When -- when David was reporting to legal.
Q. We have been advised that transactional records were purged in 2009.
Do you recall that being the case?
A. Transactional records were purged in 2009?
Q. Mm-hmm.
A. I don't recall that. I

don't -- I'm not familiar with that.
Q. Were you part of any decision to purge any records that might relate to transactions or DEA reporting requirements in 2009 or at any time?
A. No. I was not involved.
(Document marked for identification as Exhibit Schein-DiBello-10.)
BY MR. MIGLIORI:

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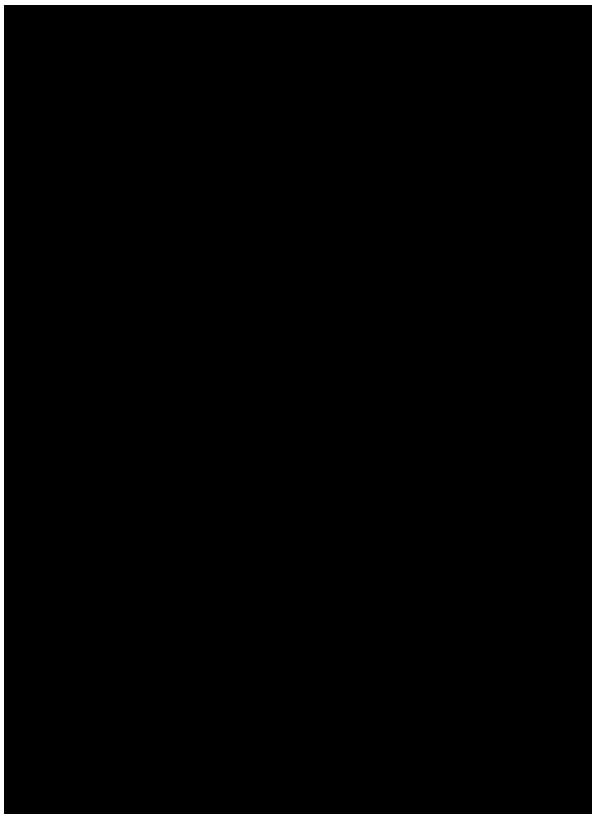
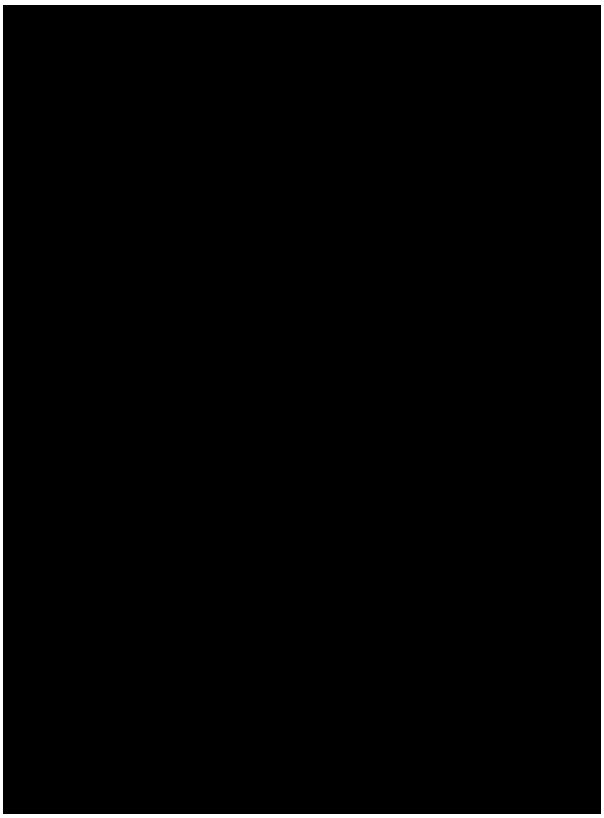
Page 110



Page 112



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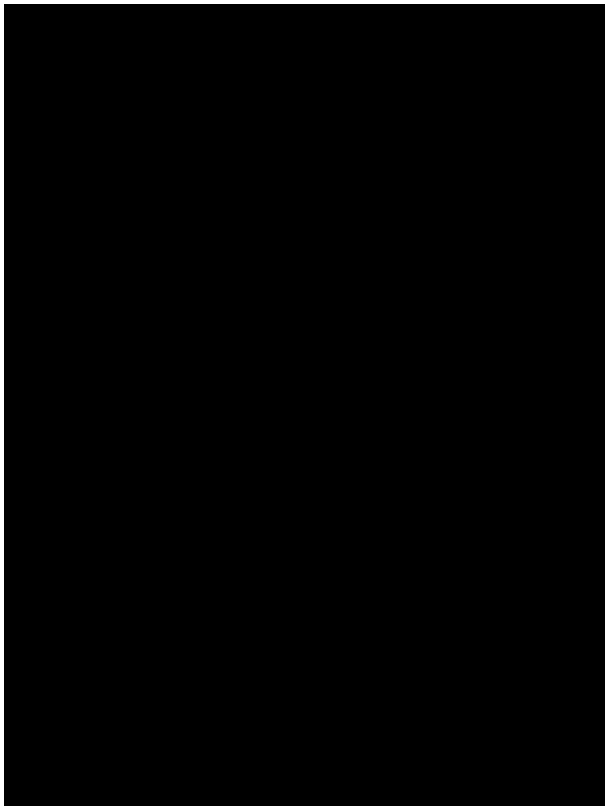

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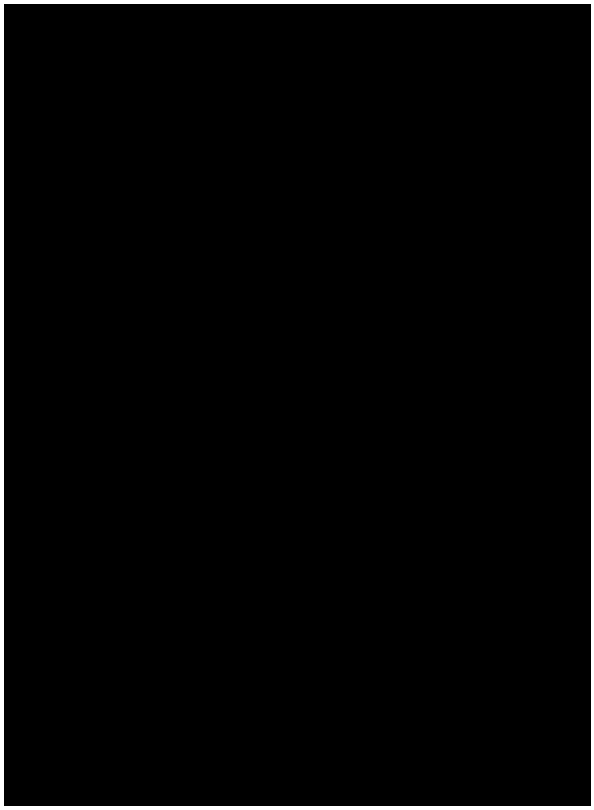

Page 114

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Page 115

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Page 116

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Page 117

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BY MR. MIGLIORI:

Q. All right. Consistent with the timeline that we looked at before that you had in your PowerPoint presentation, it was around September 20 of 2007 that you reported to the trade association along with Buzzeo that Henry Schein started its SOM project.

Do you recall that?

MR. McDONALD: Object to the form.

THE WITNESS: Point of clarification. This was the Ron Buzzeo annual meeting, not the trade association.

BY MR. MIGLIORI:

Q. Okay. On the front page of that, it -- it said the 7th Annual. I thought you said it was the trade association. I thought you said you reported to some of your competitors and -- and other distributors?

A. Right. But this was -- this was a Cegedim Dendrite annual controlled substance conference, not a trade association.
Q. Okay. So it was Buzzeo's conference --
A. It was Buzzeo's conference.
Q. But -- but a bunch of different distributors were there?
A. There were -- there were distributors.
Q. It was -- it wasn't a trade association apparently.
A. It wasn't a trade association.
Q. But you did present at that conference, that, in fact, in September of 2007, Henry Schein started the SOM project.
MR. McDONALD: Object to the form. Mischaracterizes the document.
BY MR. MIGLIORI:
Q. Right? Well, you can read

the timeline --
MR. McDONALD: Correct. It doesn't say A.
BY MR. MIGLIORI:

[redacted]

[redacted]

But to do that, I'm going to refer you back to -- is it Exhibit 3. Can you just look at the front page of your timeline, the one that's in your hand? What's the exhibit number?
A. Exhibit 5.

Q. All right. Exhibit 5. In your PowerPoint that you prepared and you presented to Buzzeo's conference, you actually picked a date of 9/20/2007. Do you see that?
A. Yes, I didn't -- I didn't pick the date. I didn't prepare --
Q. You presented the date.
A. I presented it, correct.
Q. And in that it says, "Suspicious order monitoring project started."
That's what your presentation said, correct?
A. That's what it says.

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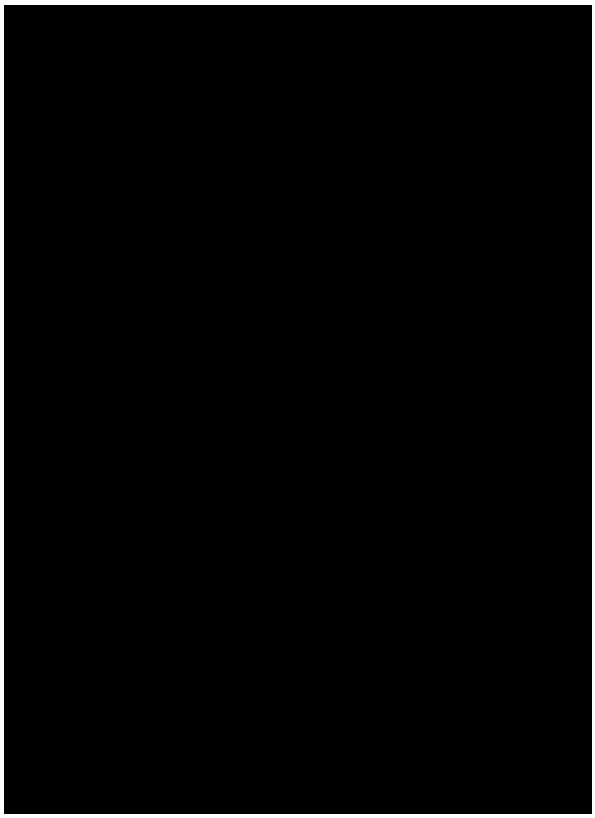
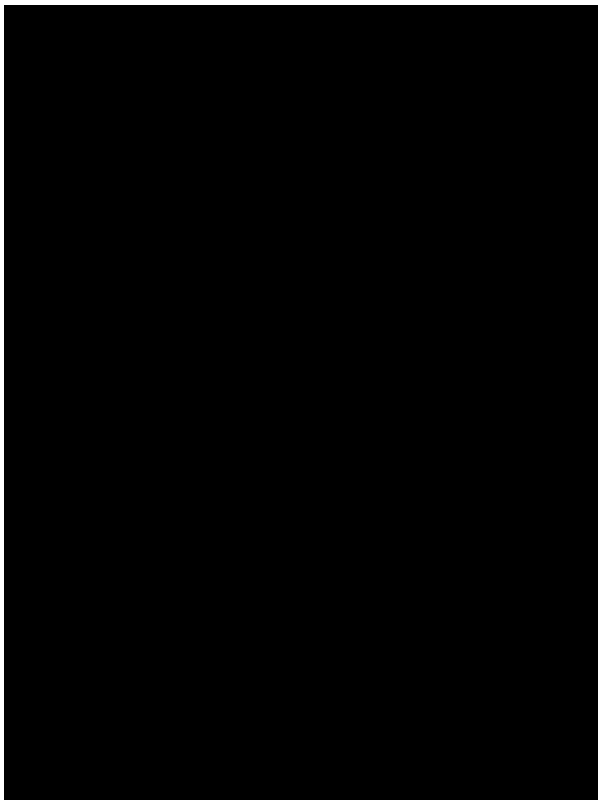
Page 122



Page 124



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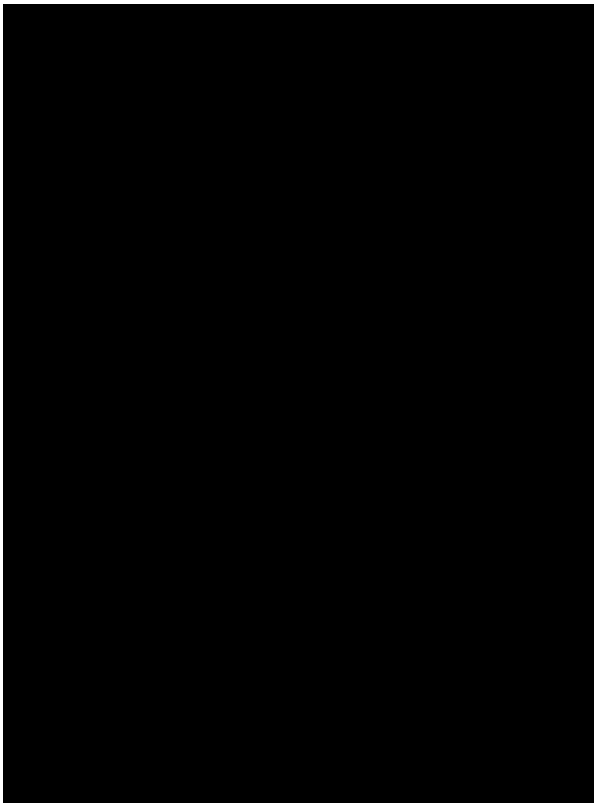

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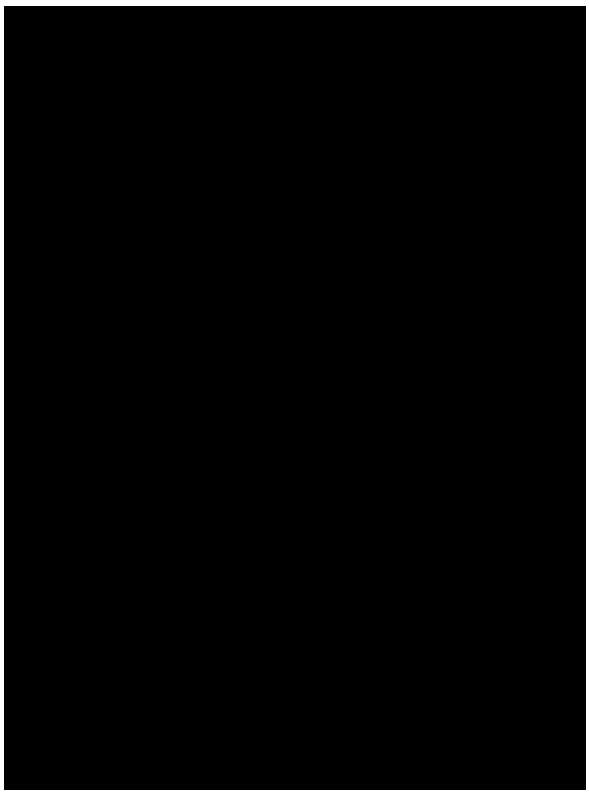

Page 126

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BY MR. MIGLIORI:
Q. Okay. Now, around this same time, there was an HDA meeting with the

Page 127

HDMA meeting with the DEA. This is in Exhibit Number 11.
(Document marked for identification as Exhibit Schein-DiBello-11.)
BY MR. MIGLIORI:
Q. Do you recall ever attending a meeting with the DEA or the HDMA?
MR. McDONALD: Object to the form.
THE WITNESS: There were several meetings with HDMA. They would meet regularly with their membership. So I attended those meetings, not all of the meetings, but I would attend some of the meetings.
BY MR. MIGLIORI:

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Page 128

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Page 129

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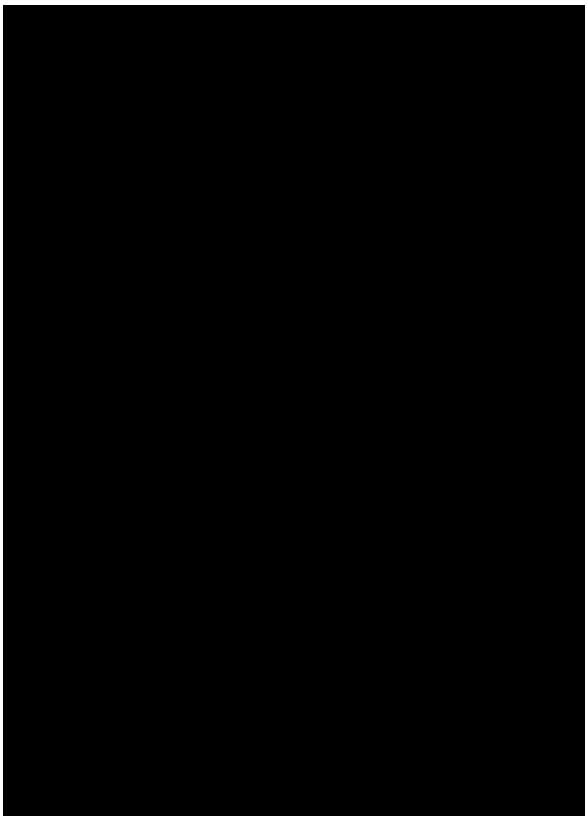
Page 130



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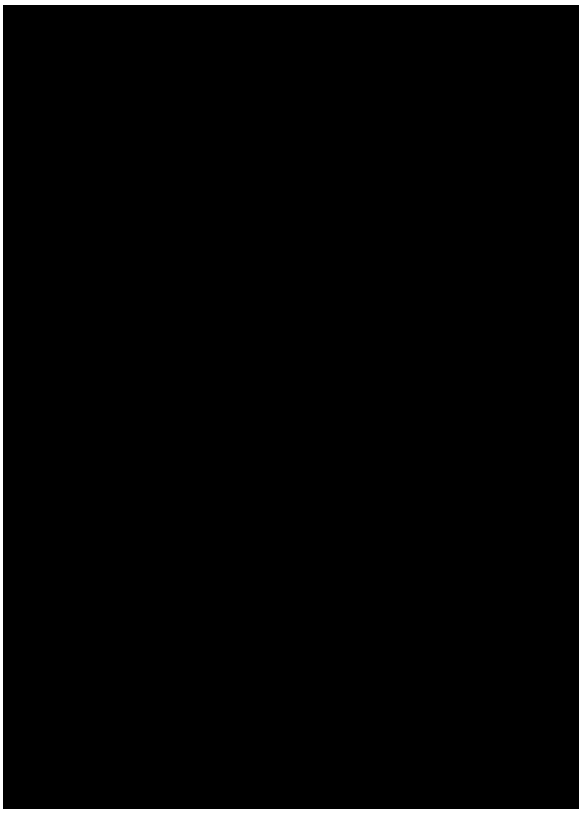

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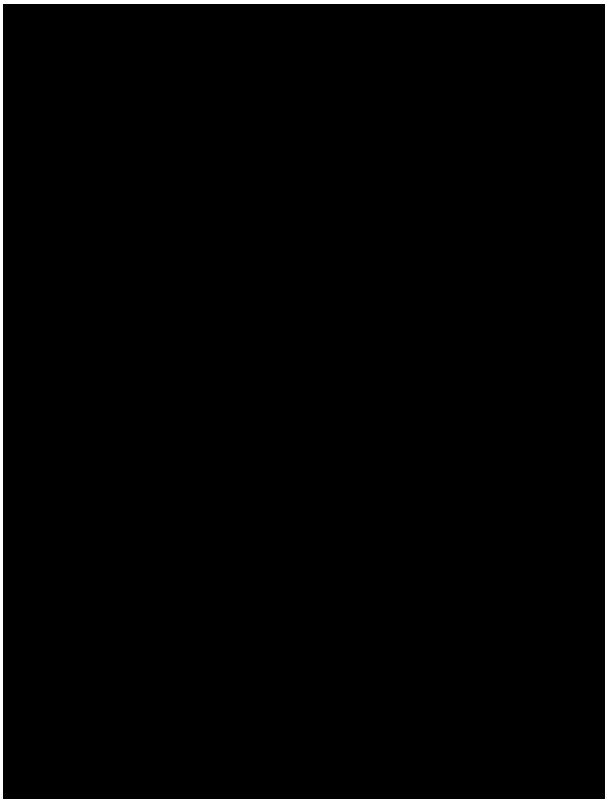
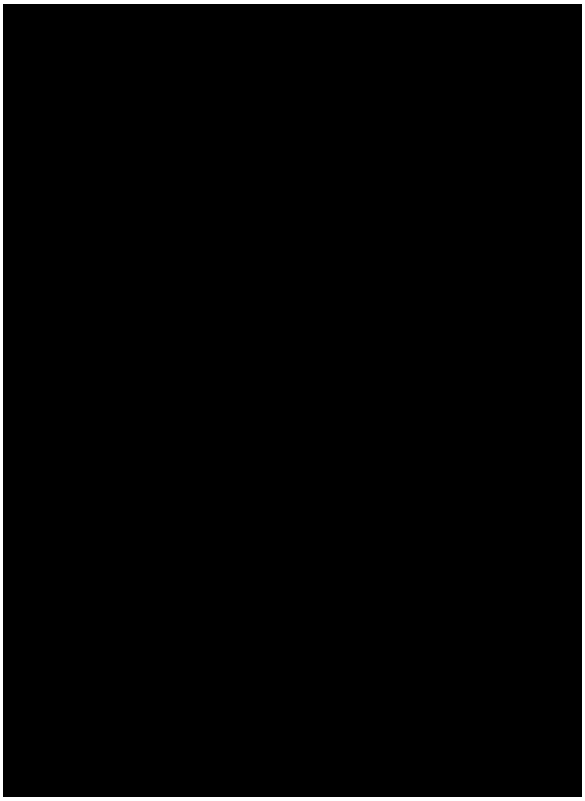


Page 133



Page 134

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Page 135

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Page 136

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MR. McDONALD: Are you

Page 137

moving to a new document?
MR. MIGLIORI: What's that?
MR. McDONALD: Are you moving to a new document?
MR. MIGLIORI: I think so.
MR. McDONALD: Why don't we take a lunch break.
THE VIDEOGRAPHER: Remove your microphones. The time is 1:58 p.m. Off the record.
- - -
(Lunch break.)
- - -
THE VIDEOGRAPHER: We are back on the record. The time is 1:49 p.m.
- - -
AFTERNOON SESSION
- - -
EXAMINATION (Cont'd.)
- - -
(Document marked for identification as Exhibit Schein-DiBello-12.)

BY MR. MIGLIORI:

Q. Mr. DiBello, let me show you Exhibit 12. Now, as I understand the way it worked between regulatory affairs and verifications, the relationship with Buzzeo was mostly facilitated through regulatory affairs, is that fair?

A. Correct.

Q. And in 2005, you were the director of regulatory affairs, correct?

A. In 2005, I believe I was the director of regulatory. I don't remember the exact date when it happened. But it's -- 2005 seems correct.

Q. Okay. And so if Buzzeo did a report in 2005, then it's something that you would have at least received, if not been the recipient of?

A. Correct.

[redacted]

[redacted]

Q. And what did you understand her role to be?

A. She was the person that was going to be our primary point person that Buzzeo selected for this project.

Q. Okay. So in 2005, you would have interacted directly with her as Buzzeo was reviewing the suspicious order monitoring procedure and process?

A. I don't recall interacting directly with her. I'm sure I had probably a meeting with her, but I wouldn't say I interacted with her on a regular basis.

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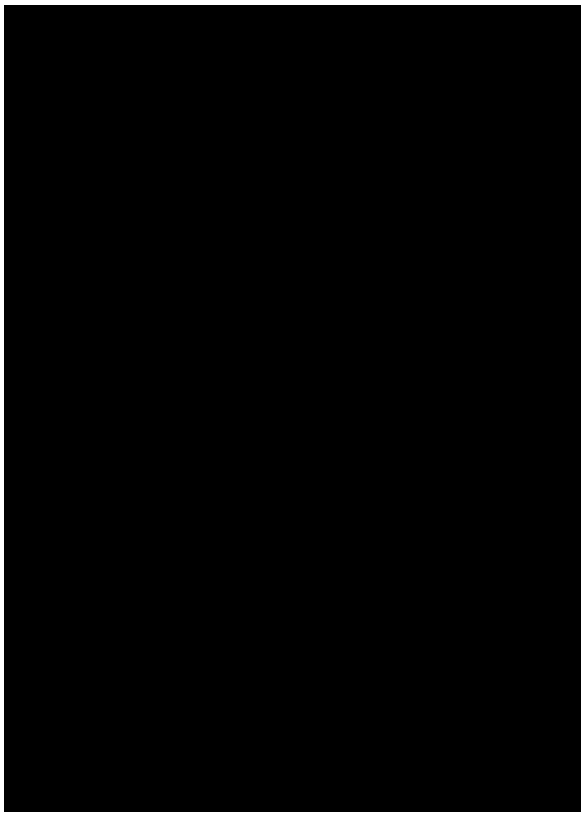
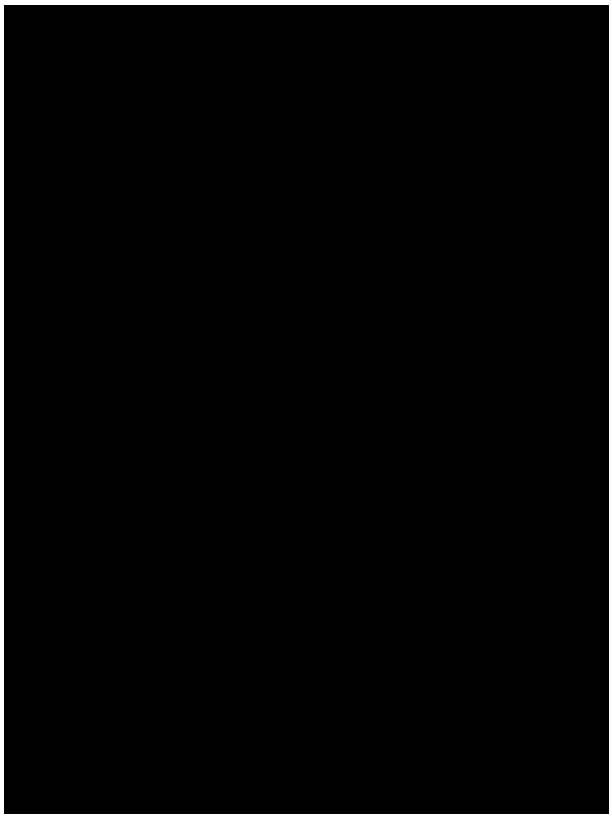
Page 142



Page 144



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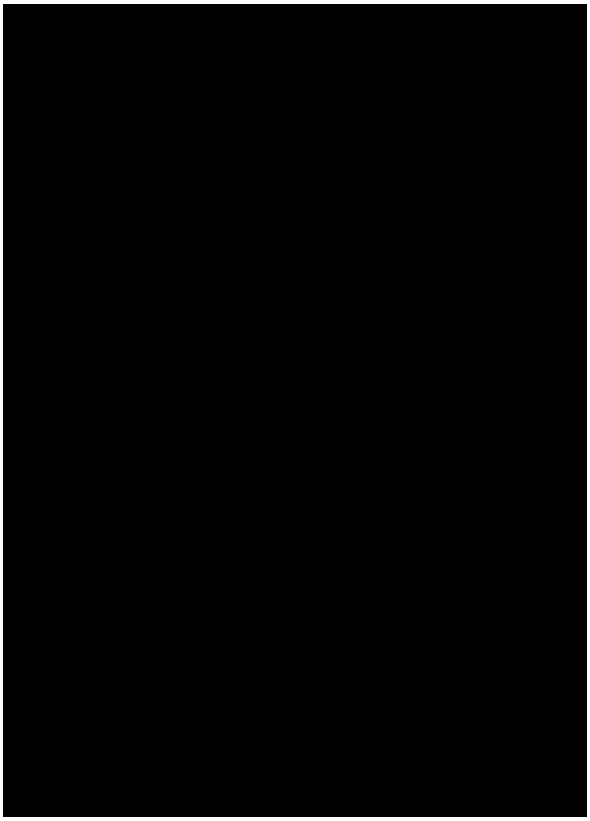

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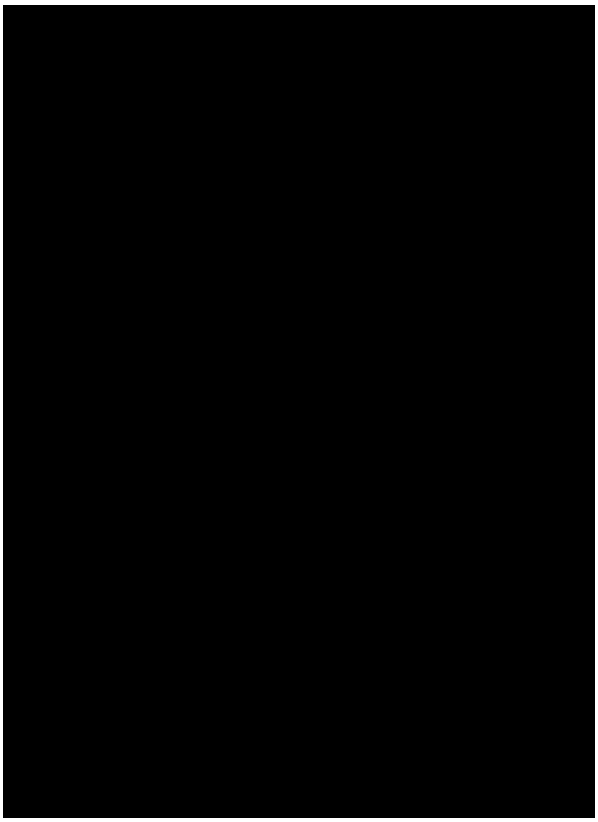

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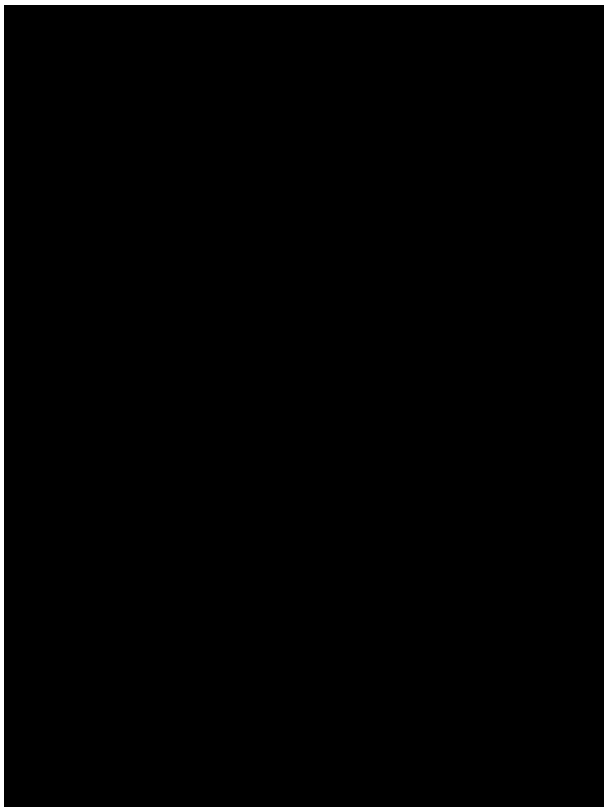
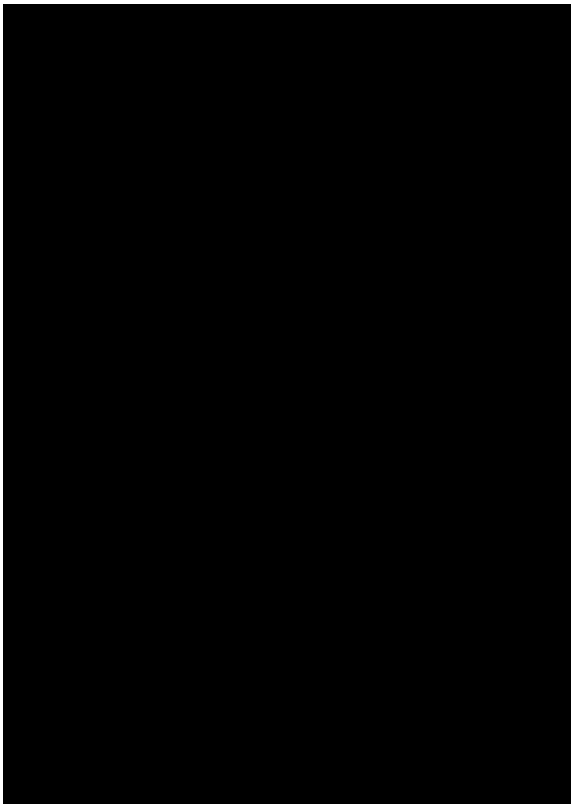


Page 148



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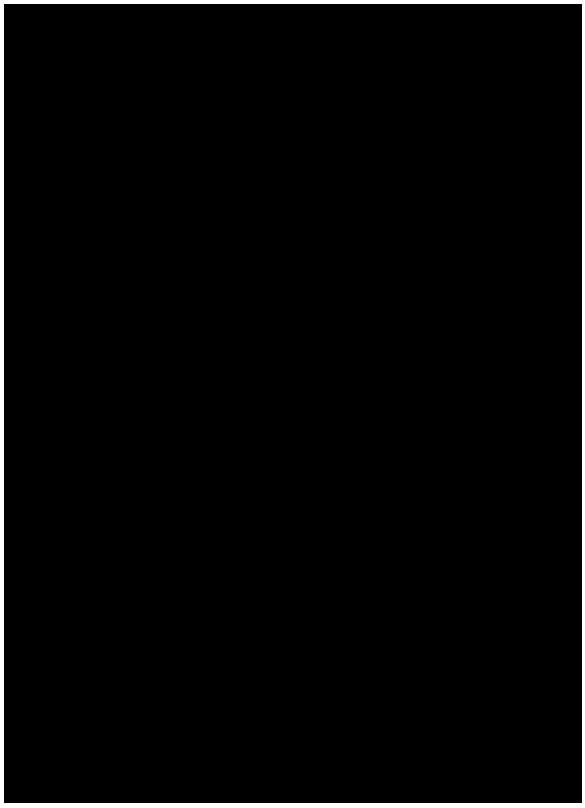

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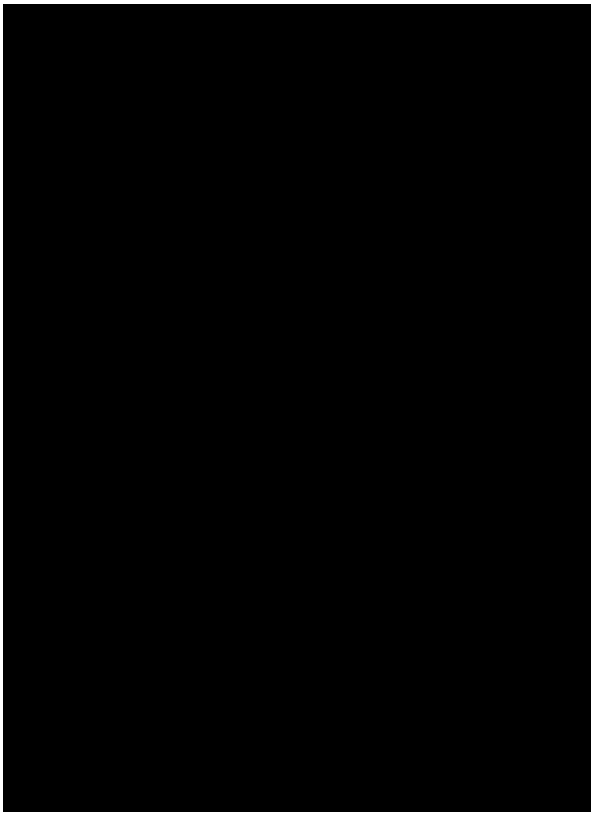

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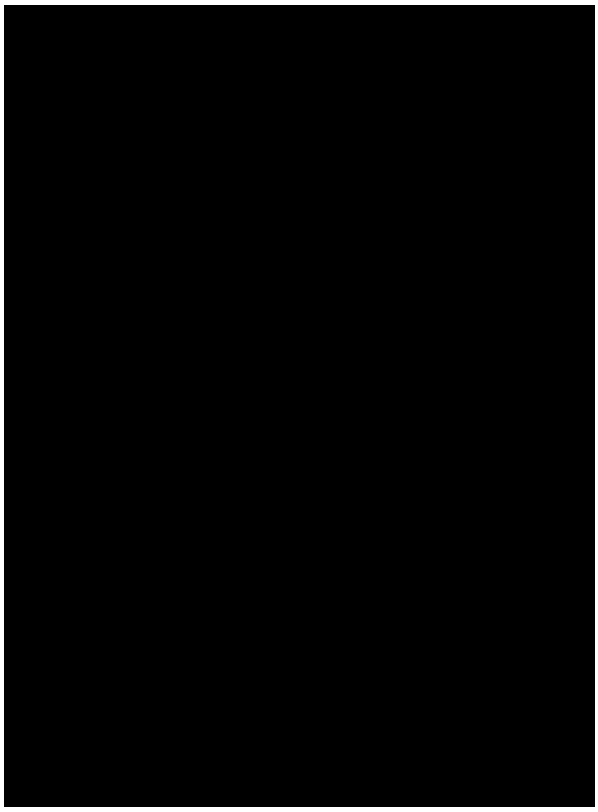
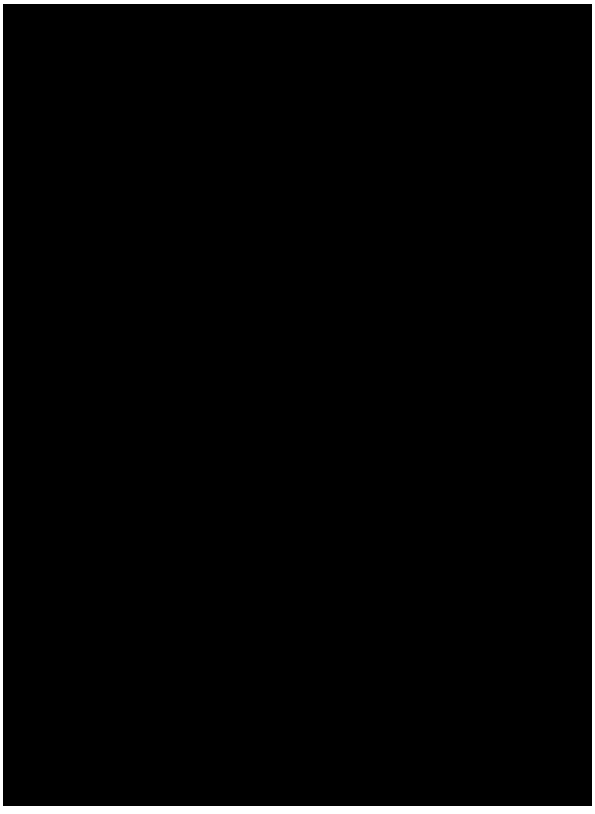


Page 151



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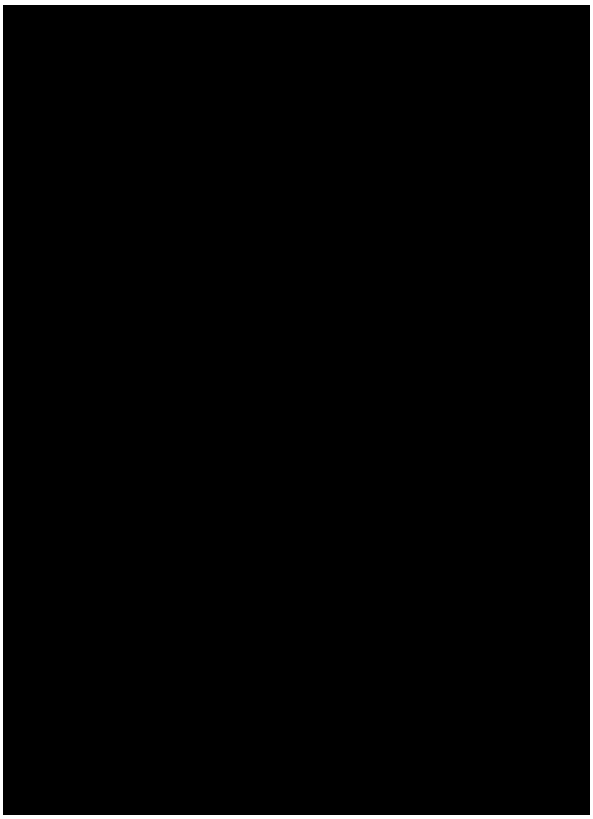

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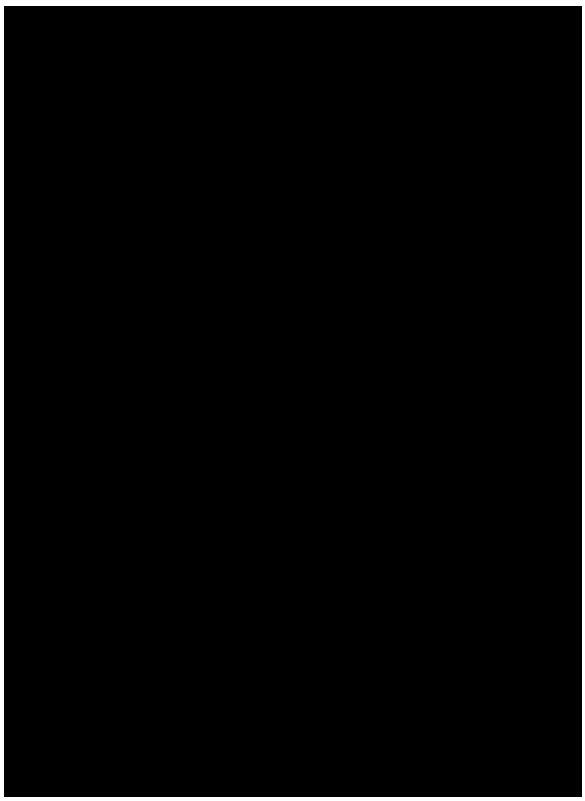

Page 154

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Page 155

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Page 156

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Page 157

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Q. Okay. Her fourth finding, "Orders that are highlighted as suspicious are all investigated. Those that are cleared from suspicious status are released. Those that are not are canceled. At the end of each month, two reports are submitted to the appropriate field office of the DEA. The first report includes those pended orders that were cleared from suspicious status. The second report reflects those orders that were deemed suspicious and canceled."

Did you understand that that was the practice through 2005 for pended and suspicious orders?

A. Yes.

Q. Did you understand though in that practice, that she recommended that suspicious orders be reported immediately and not at the end of the month. By reporting them on a monthly basis at the end of the month was inconsistent with the Controlled Substances Act requirements.

MR. McDONALD: Object to the form.

THE WITNESS: In 2005, I don't recall if that was inconsistent with the act.

BY MR. MIGLIORI:

Q. She finds -- she documents here the requirement, "The registrant shall inform the field division office of the administration in this area of suspicious orders when discovered by the registrant."

Her recommendation she writes, "While HSI has been using the current reporting process for several years, it is recommended consideration to

be given to filing the suspicious order for those orders not released from suspicious status to the DEA immediately."

Do you understand that that was the recommendation then, that reporting them at month's end was not consistent with the requirements of the Controlled Substances Act?

A. That was her recommendation.

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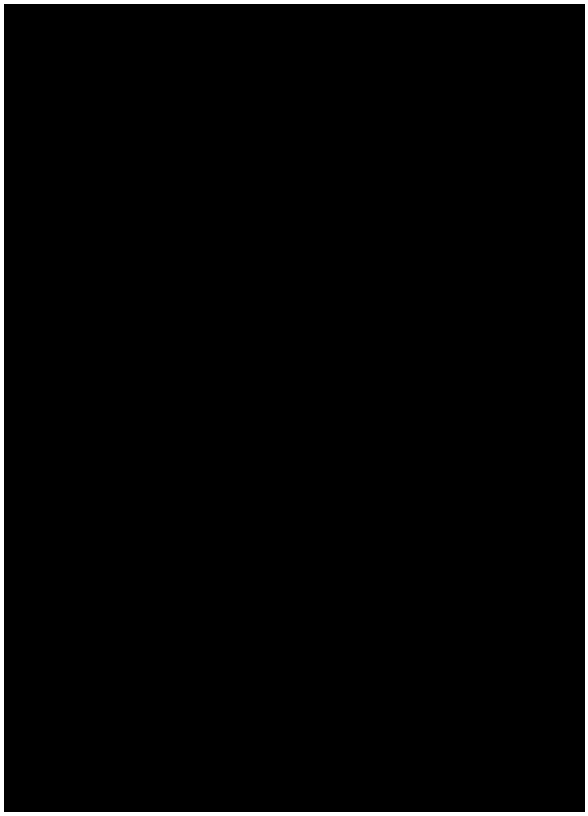
Page 162



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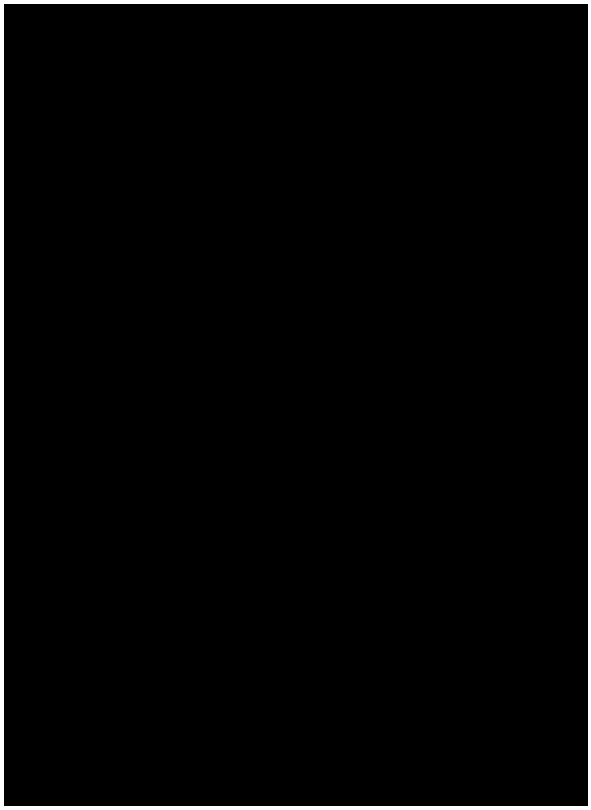
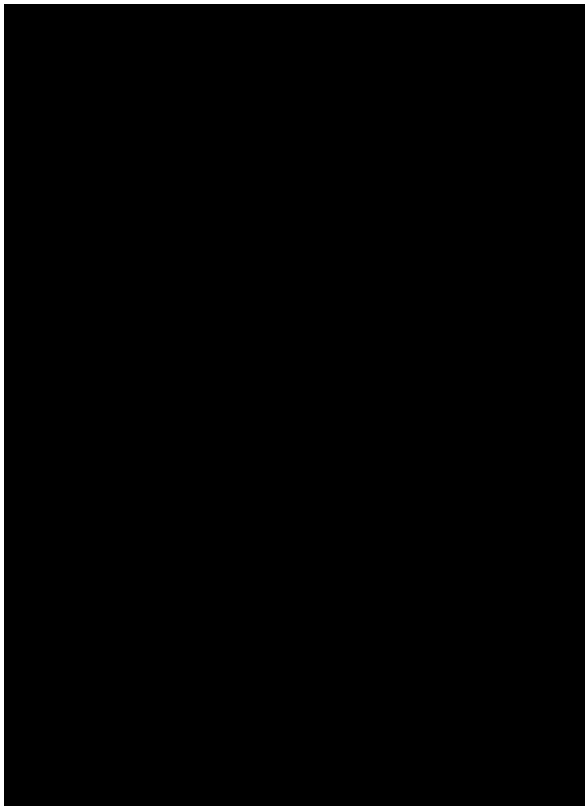


Page 163



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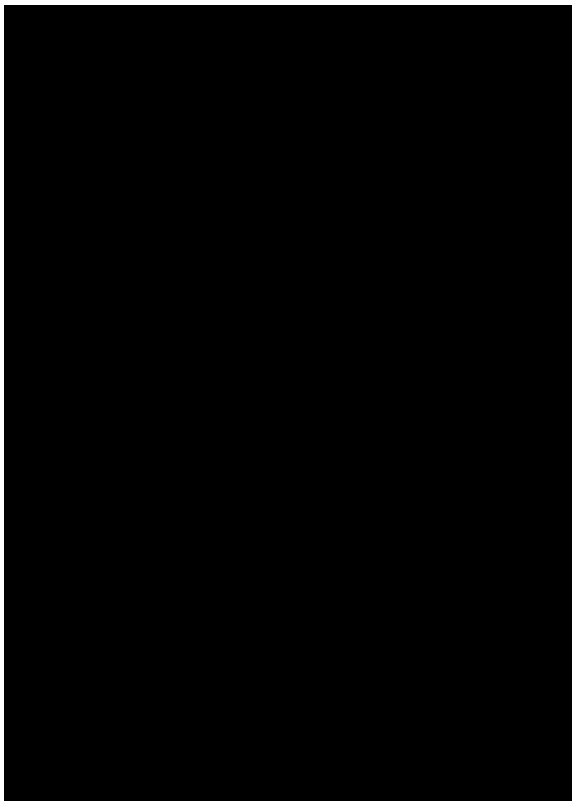

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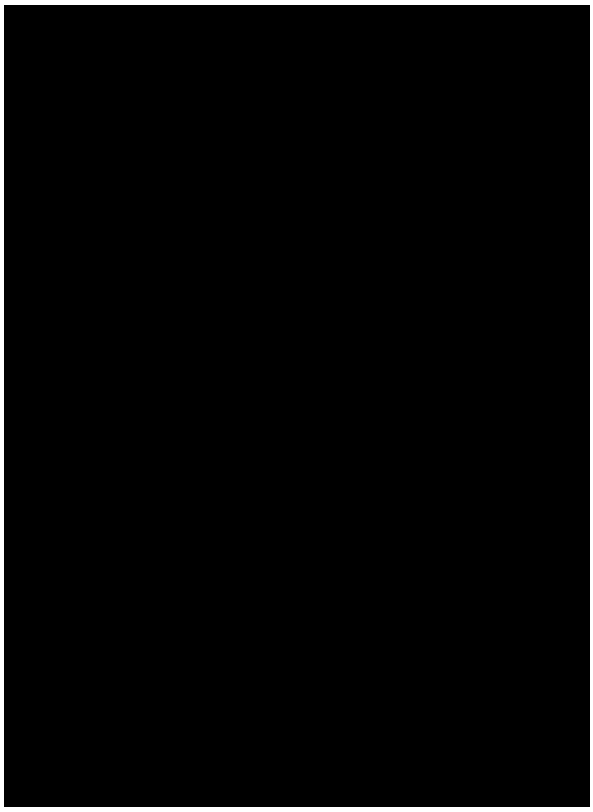

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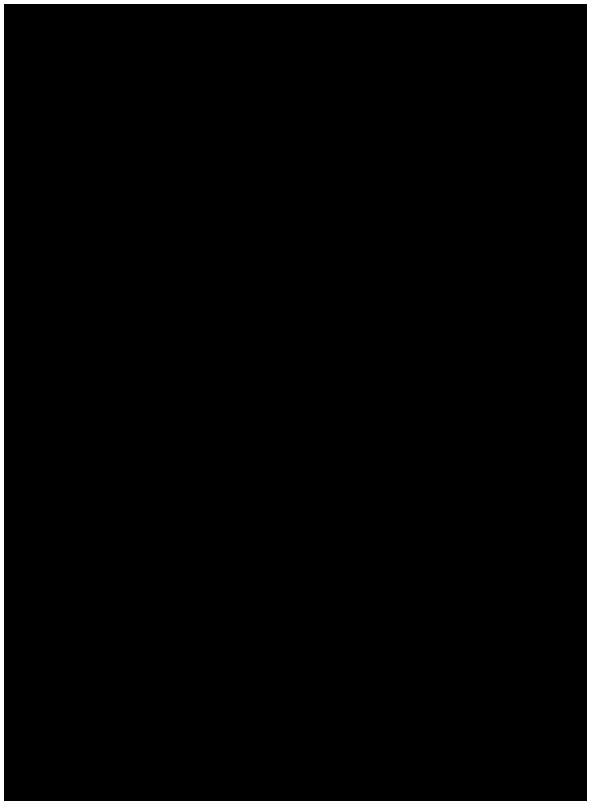

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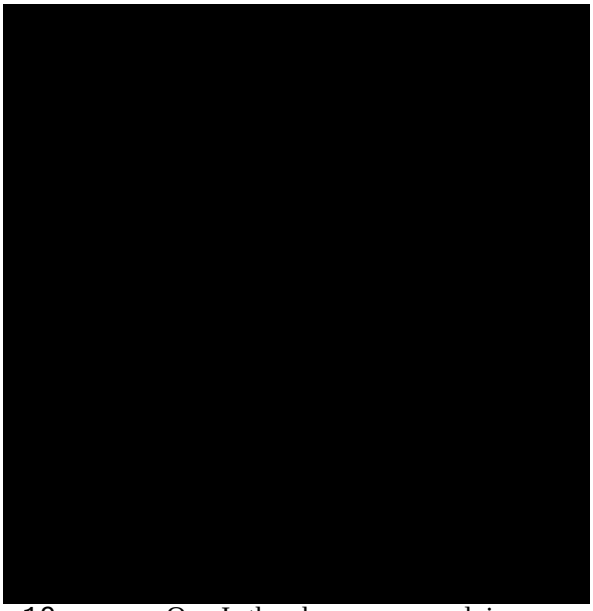

Q. Is the pharmacy complying with state laws, not just CSA. That's another "know your customer" inquiry, correct?

A. Correct.

Q. And when the word "pharmacy"

Page 169

appears here, in your practice; that is, in the Henry Schein model, that would also apply to doctors, correct, individual customers, not just pharmacies?

MR. McDONALD: Object to the form.

THE WITNESS: I'm not sure I would make that assumption.

BY MR. MIGLIORI:

Q. So you don't look at Henry Schein, what percentage of a doctor's ordering from you is controlled versus noncontrolled?

A. I didn't say that. I said I wouldn't make the assumption that a -- you know, is the pharmacy complying with laws of every state as the same as evaluating a doctor's compliance with the laws of every state.

Q. Would the word "doctor" fit in there for Henry Schein's customers? Is the doctor complying with the laws of every state in which it's dispensing

Page 170

controlled substances? Is that an important factor to Henry Schein?
A. Yes. Doctor would be --
Q. I'm sorry.
A. The doctor compliance. But we would verify a doctor's license. A doctor's practice is different than a pharmacy's operation and their compliance. That's my only point.
Q. It doesn't refer to specific laws. It just says complying with the laws of the state. You would expect your doctors to be in compliance with the laws of his or her state?
A. Absolutely.
Q. So these are concepts of know your customer that were shared with you that you would have received in 2006 from the DEA, correct?
A. Correct.

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Page 172

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Page 171

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Page 173

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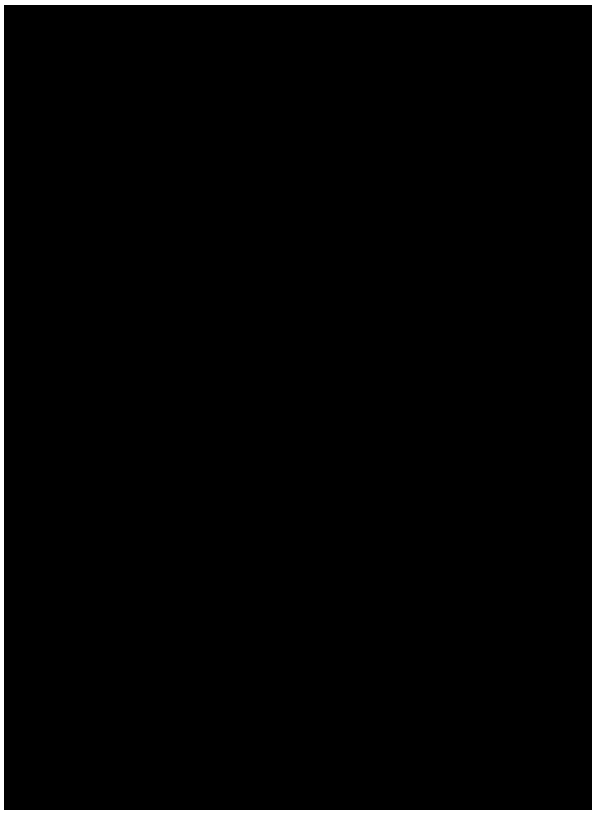
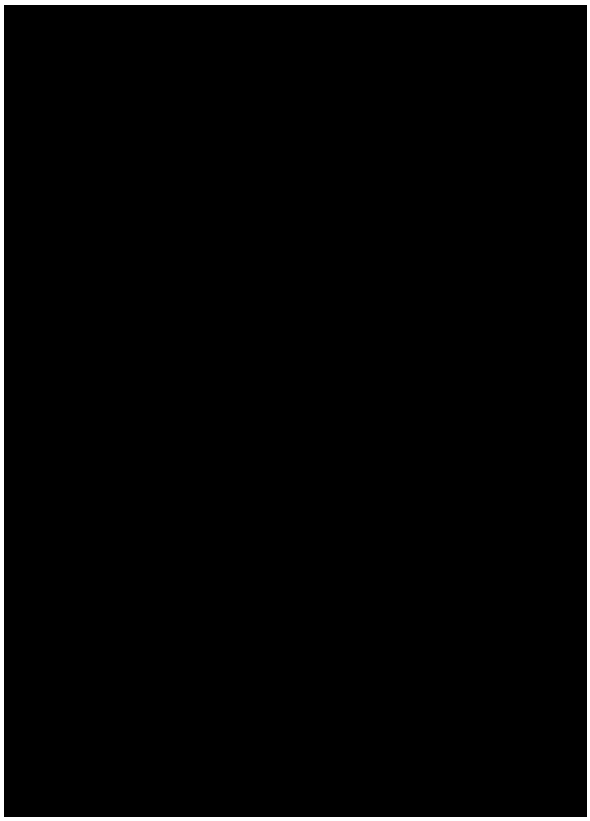
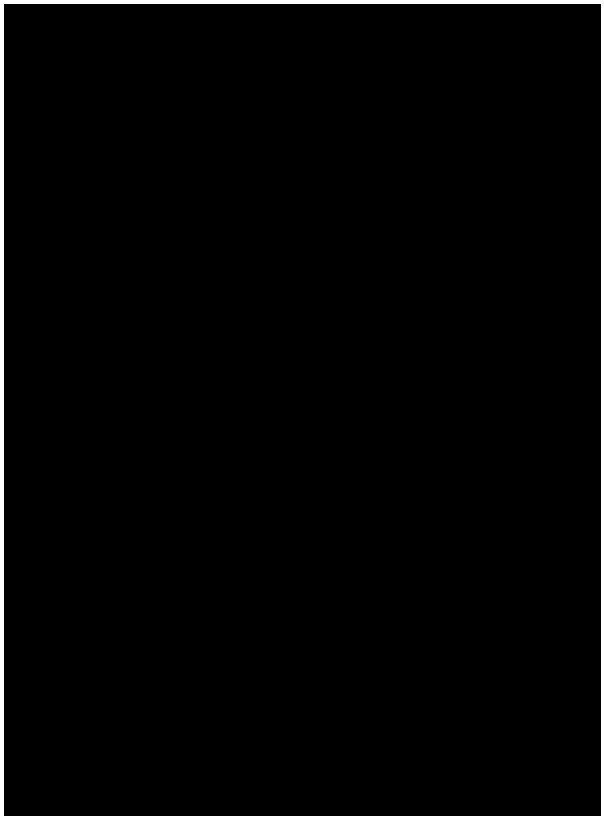
Page 174



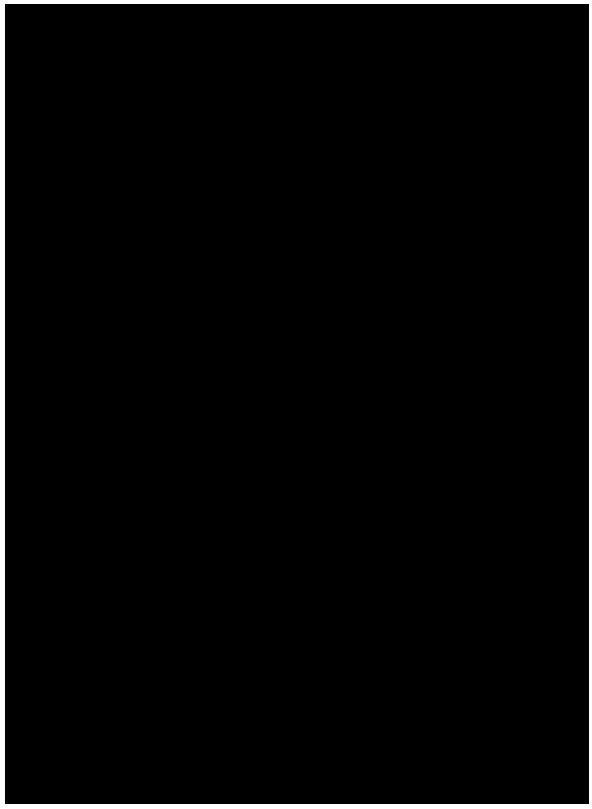
Page 176



Page 175



Page 177



Page 178

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Page 180

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Page 179

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Page 181

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Q. Well, we just went through -- I don't want to go through them again. But we just went through Buzzeo's findings in 2005, and it wasn't picking up that it needed -- there needed to be a new review of how to check orders

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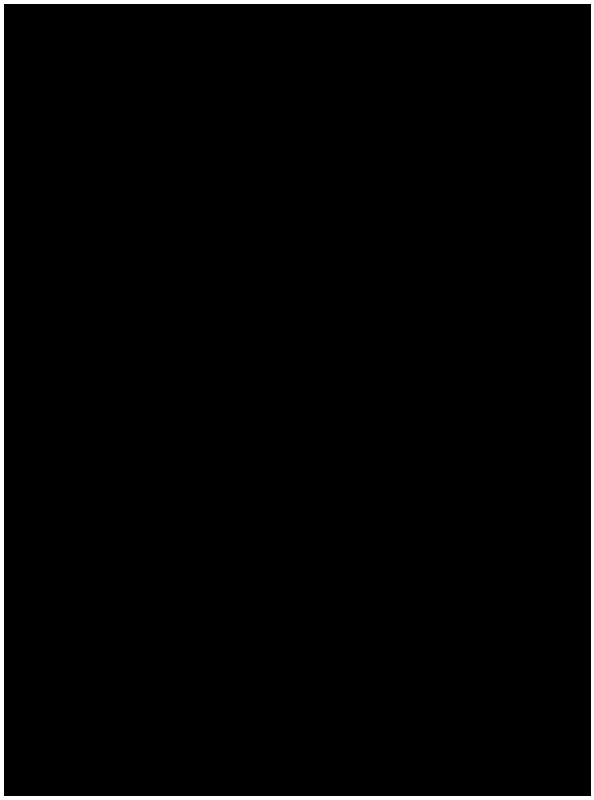
Page 182



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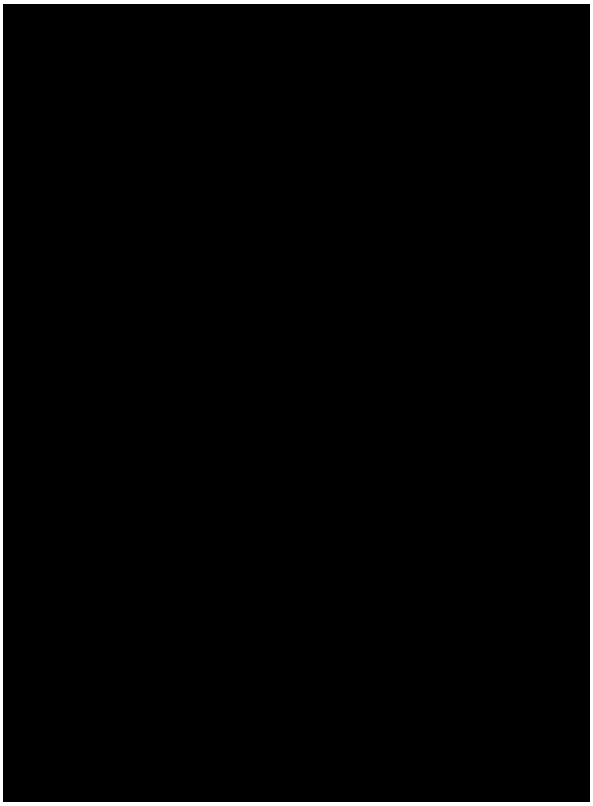

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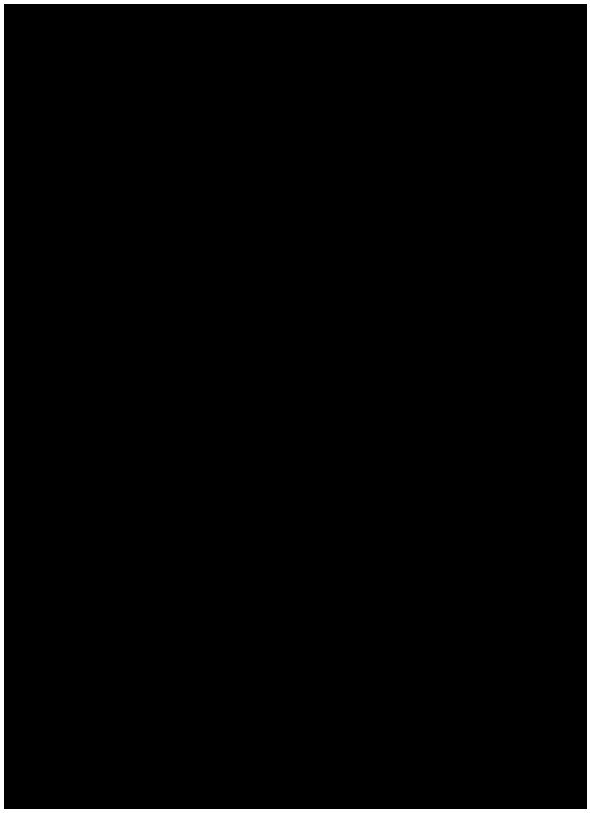

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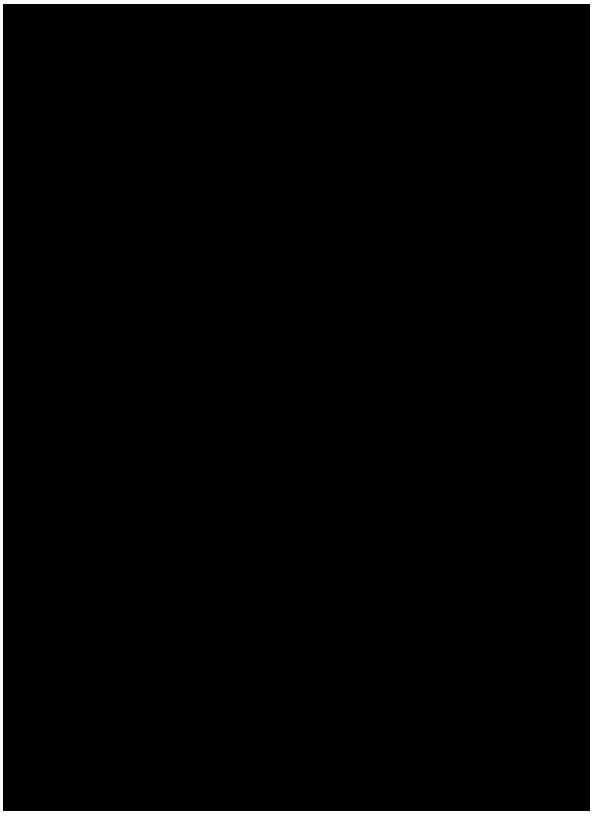

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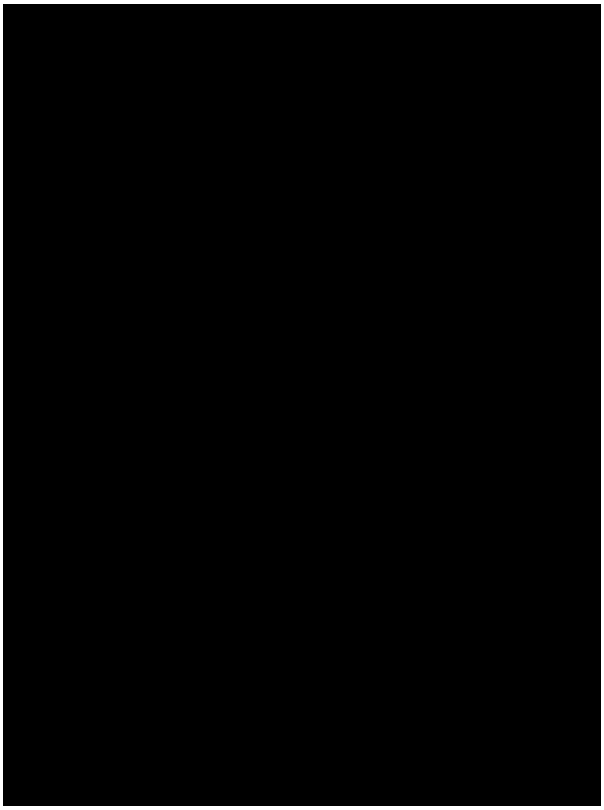

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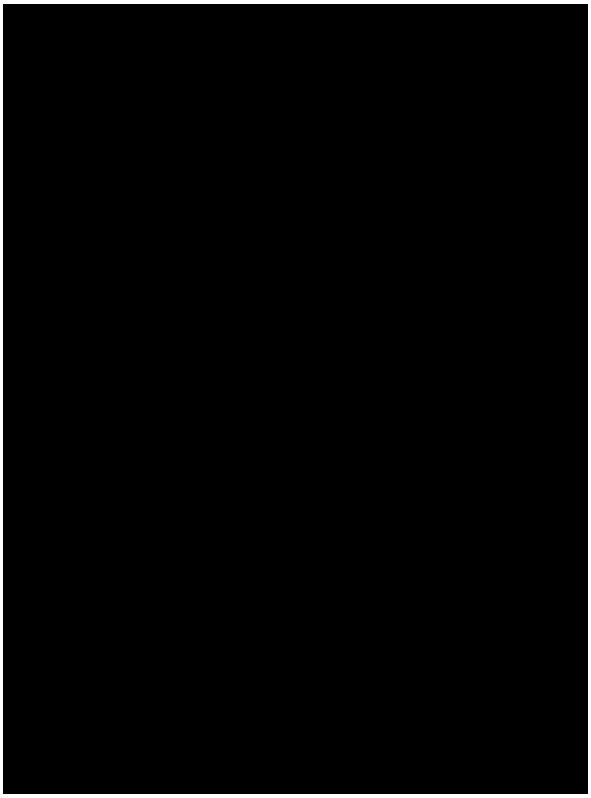
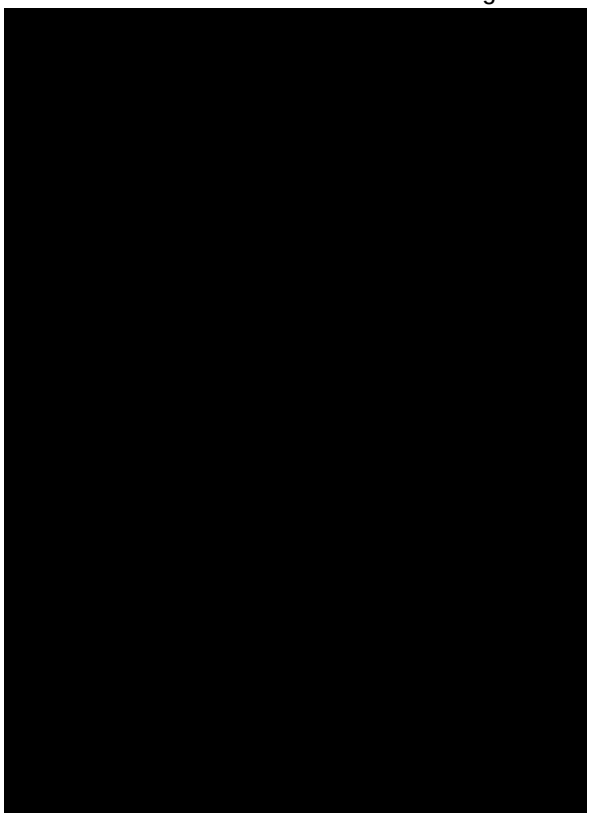


Page 187



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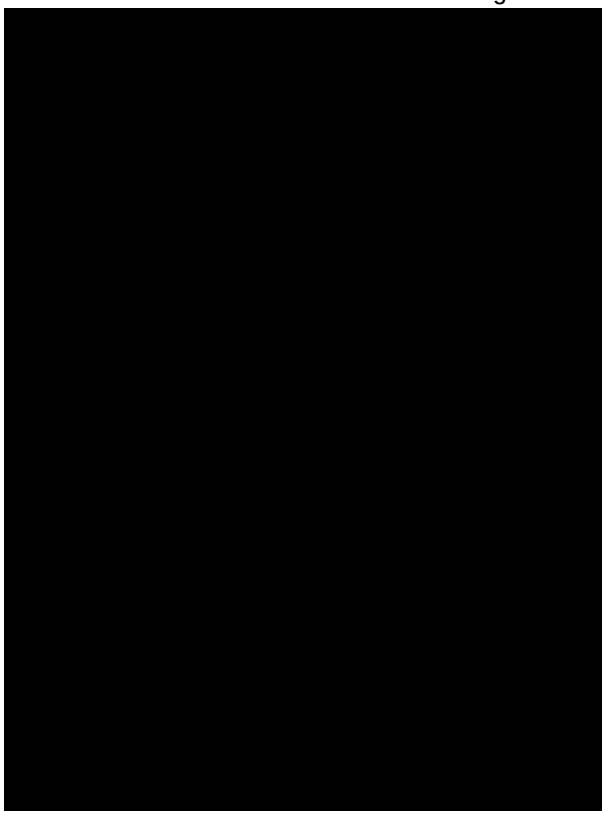

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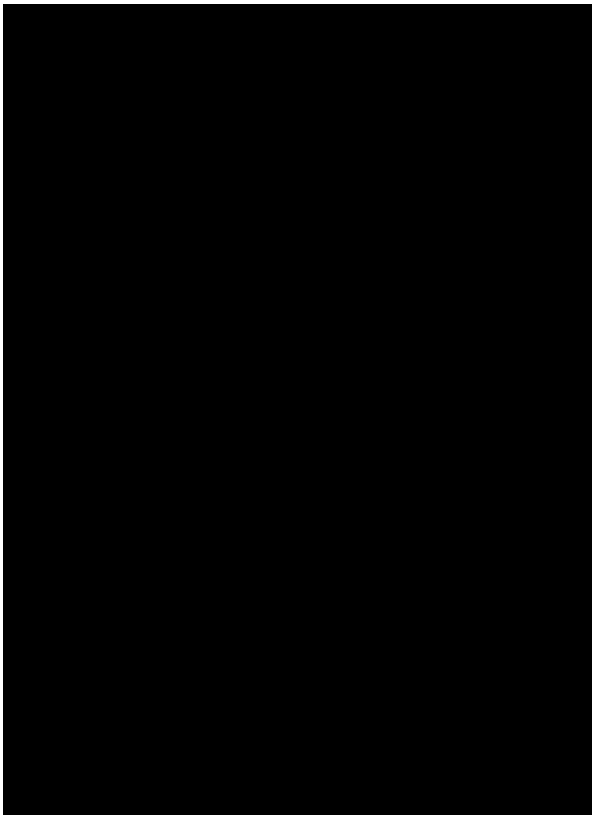
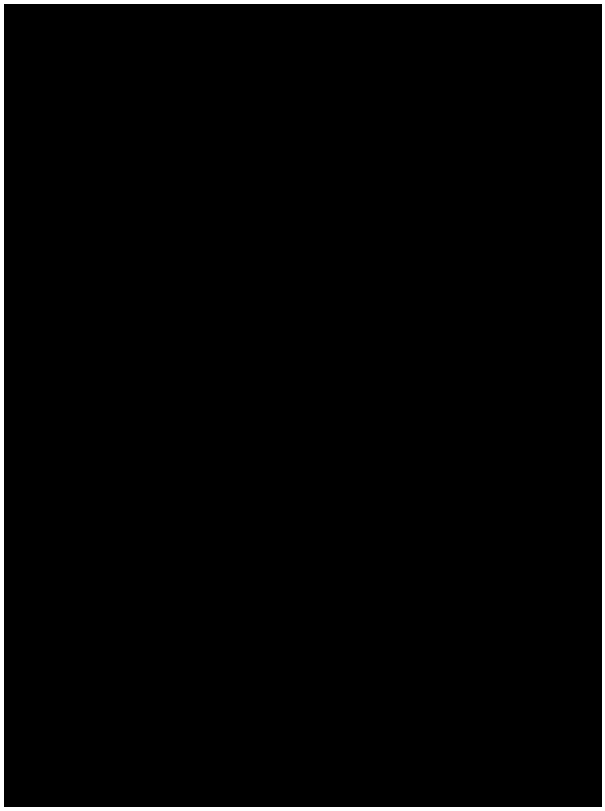


Page 192



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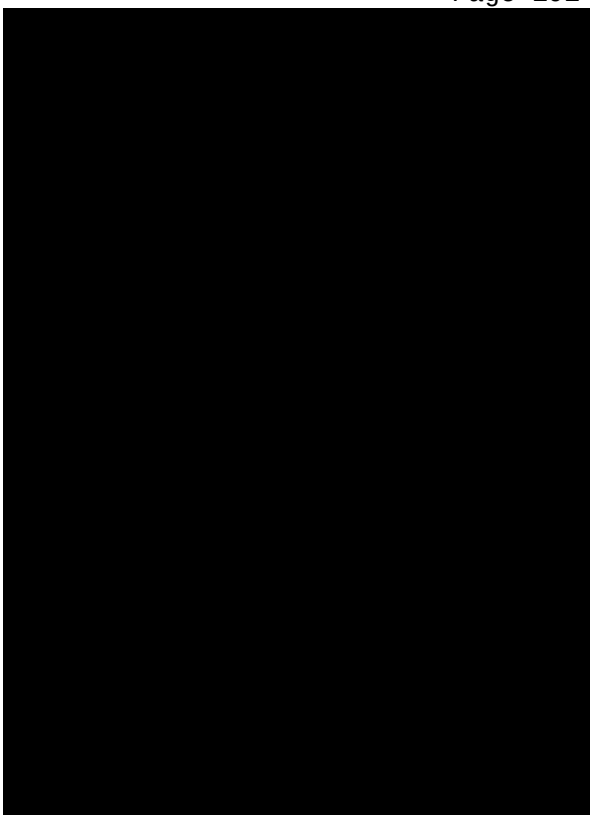

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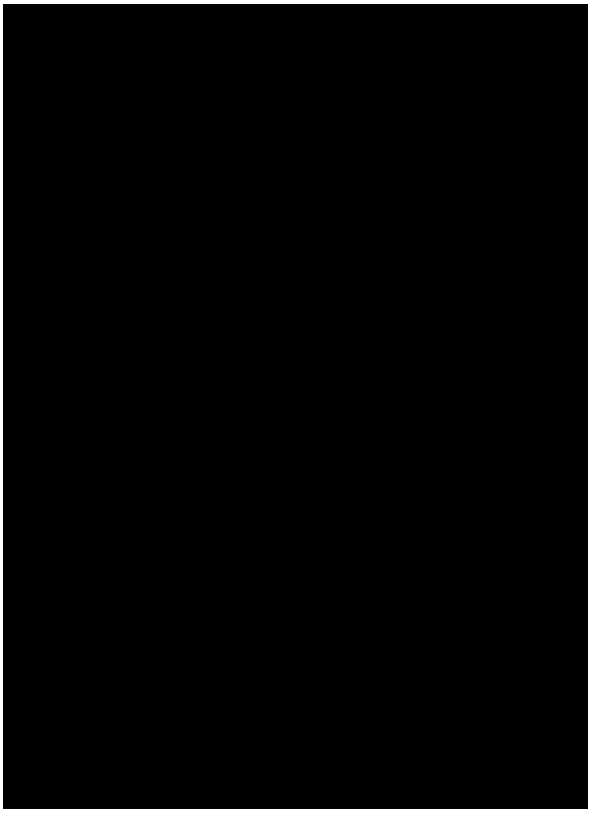

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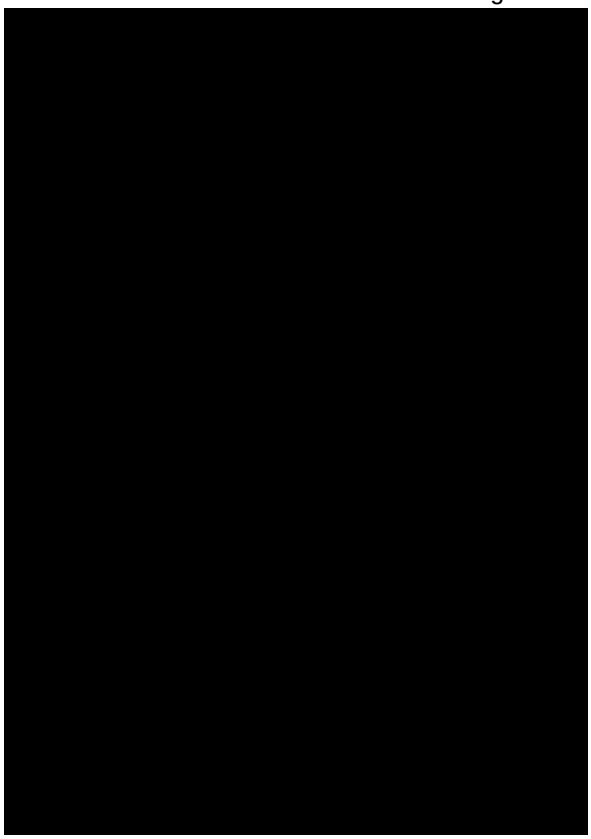

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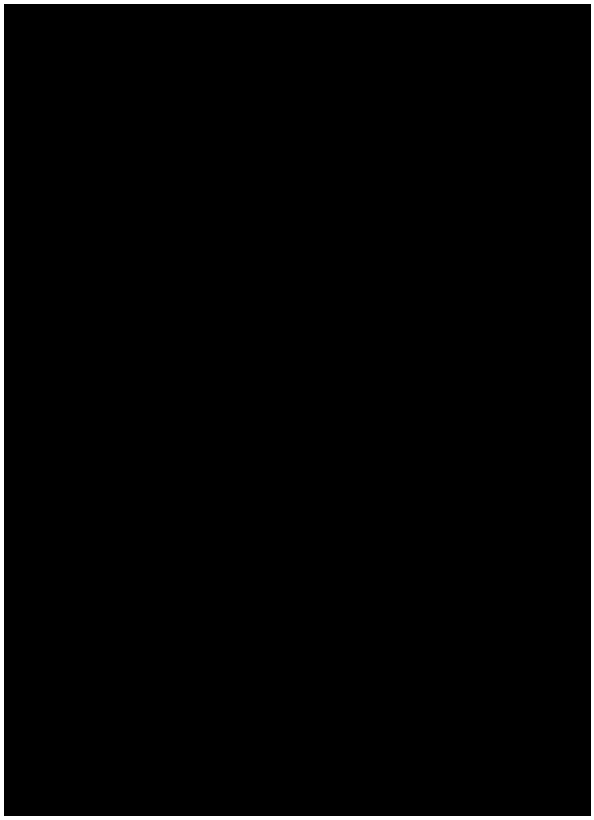

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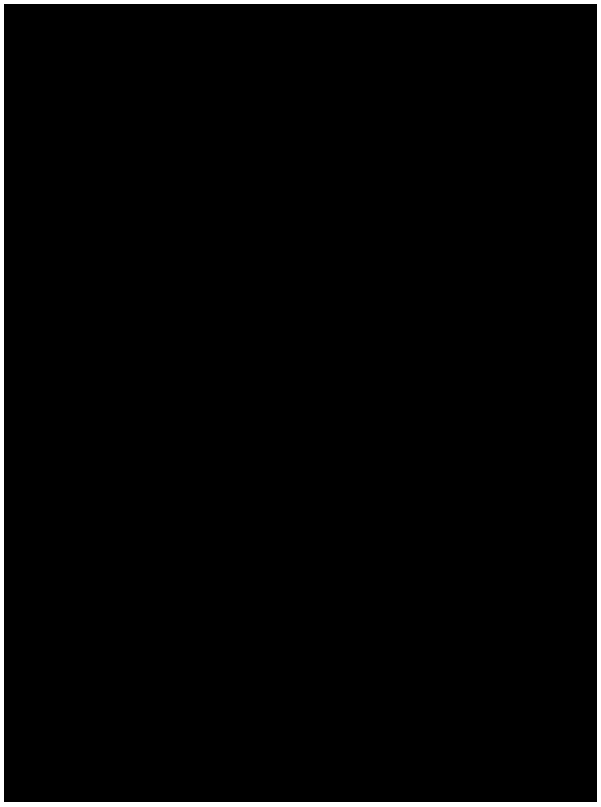

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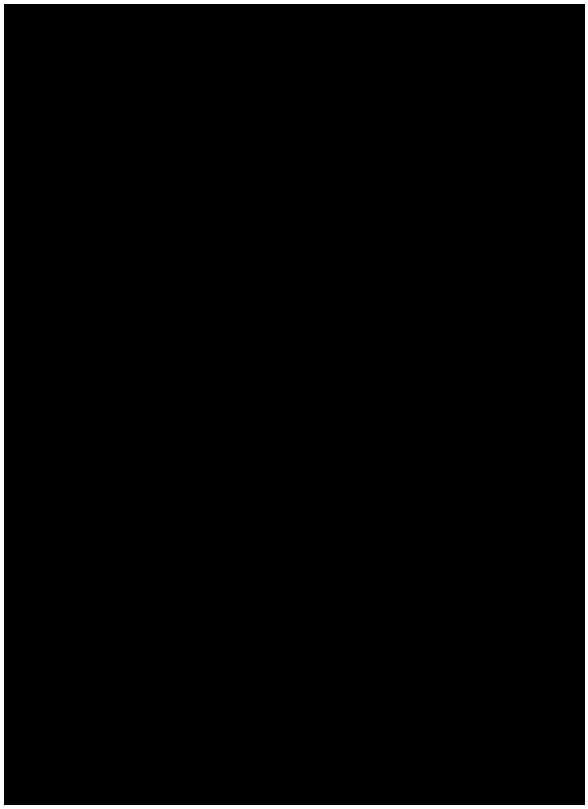

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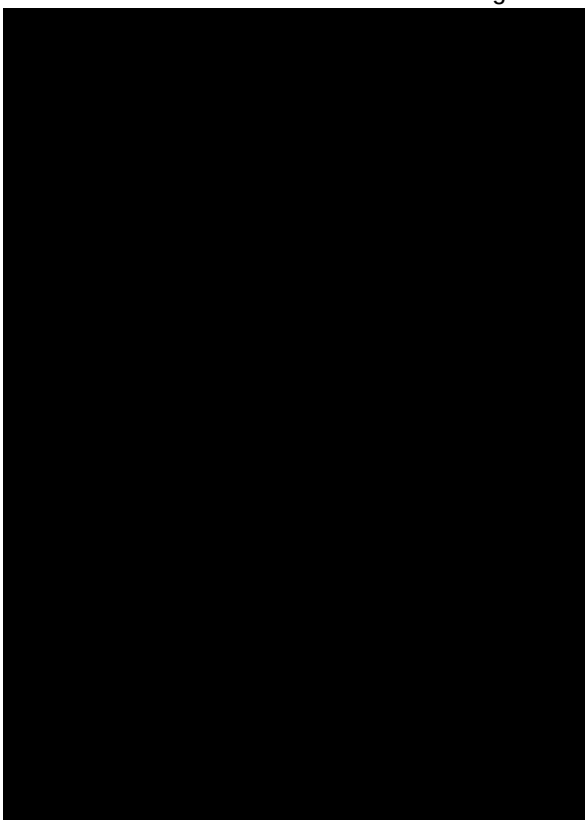

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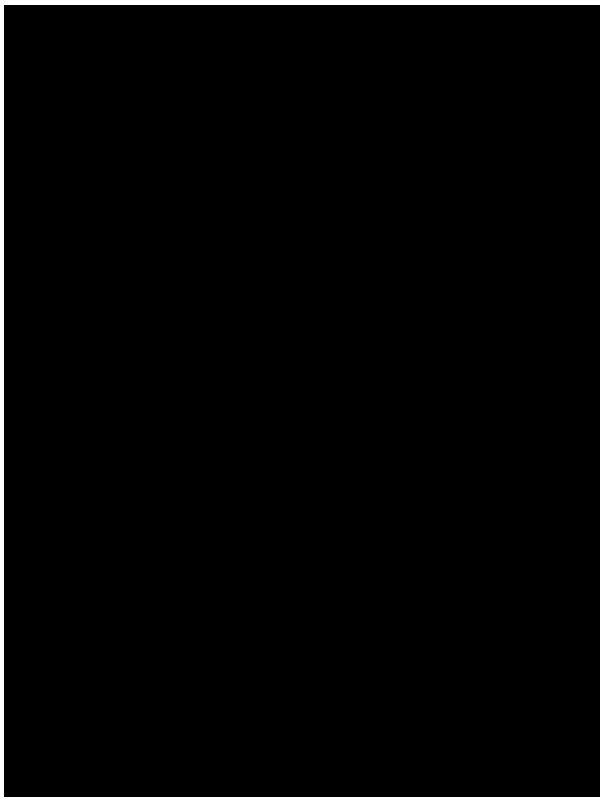

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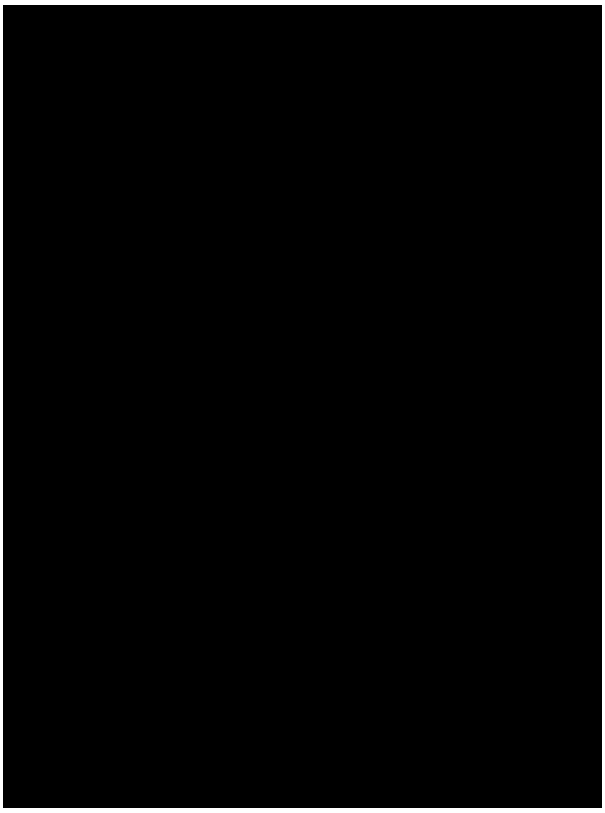

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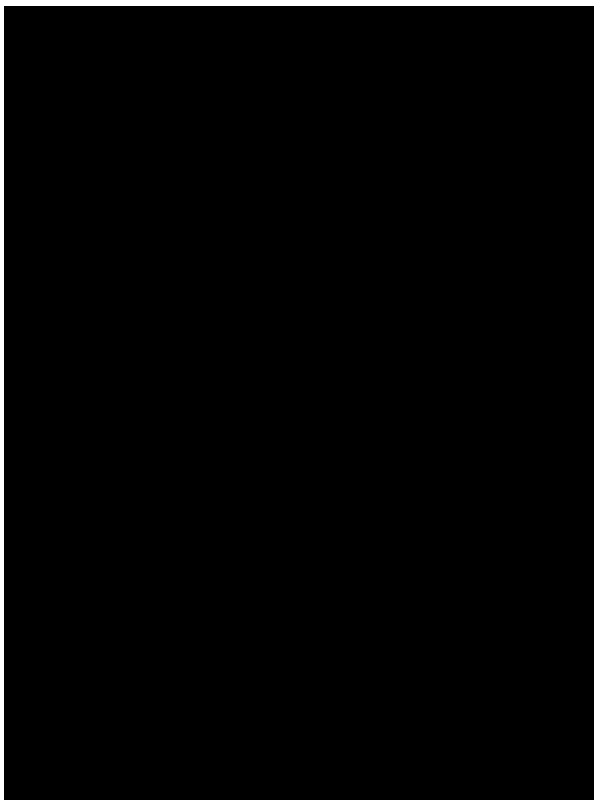

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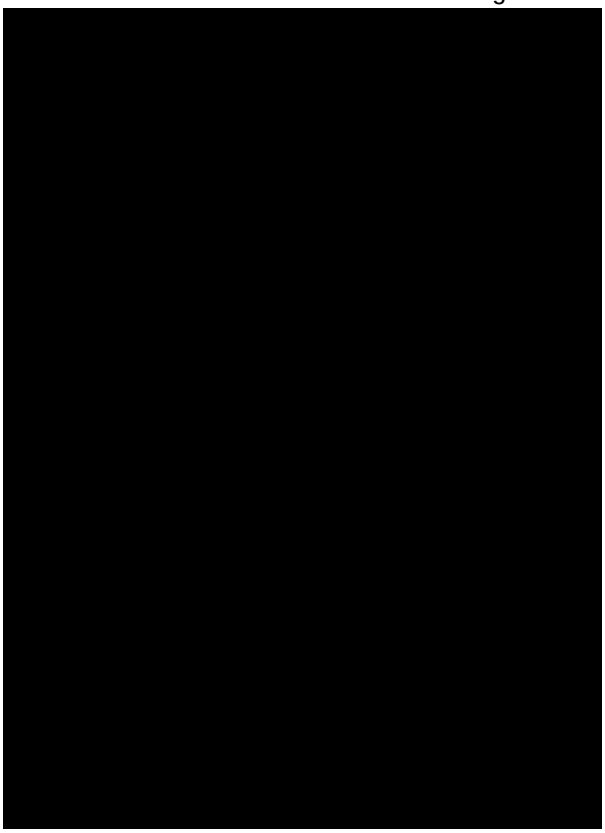

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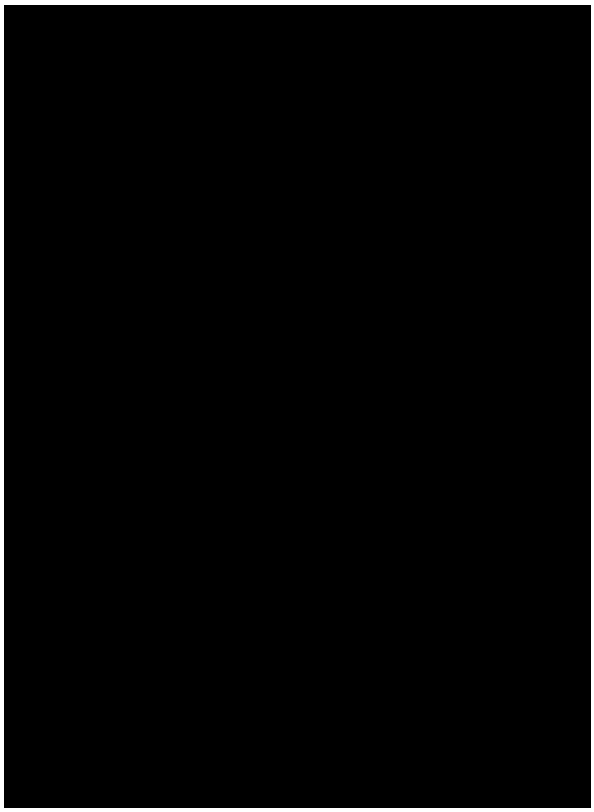

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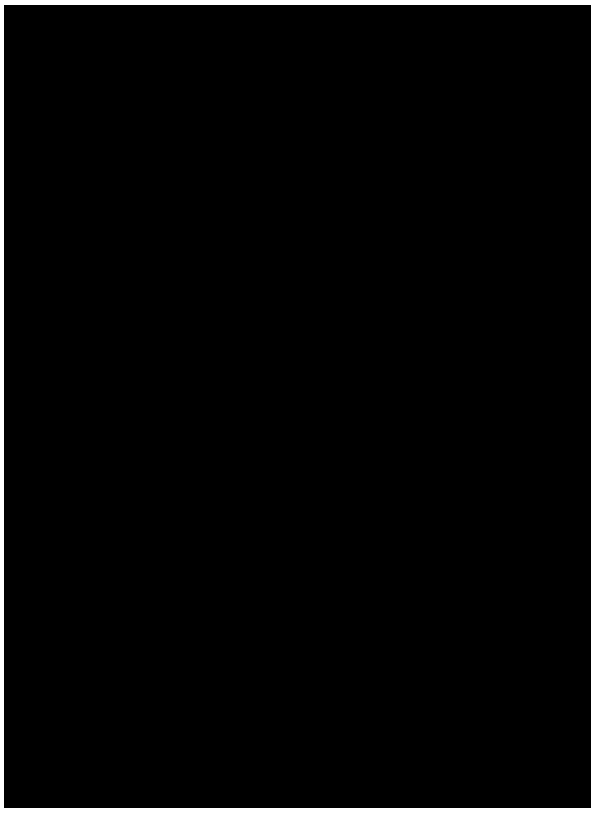

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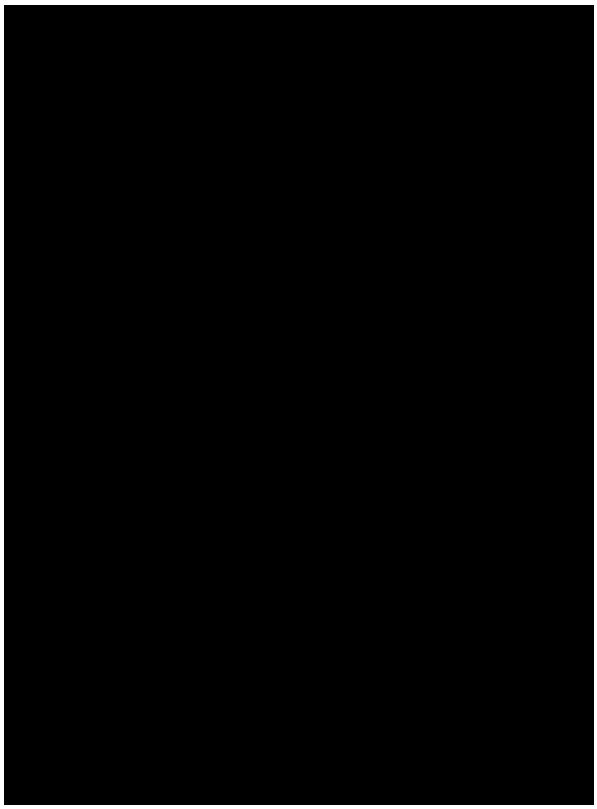

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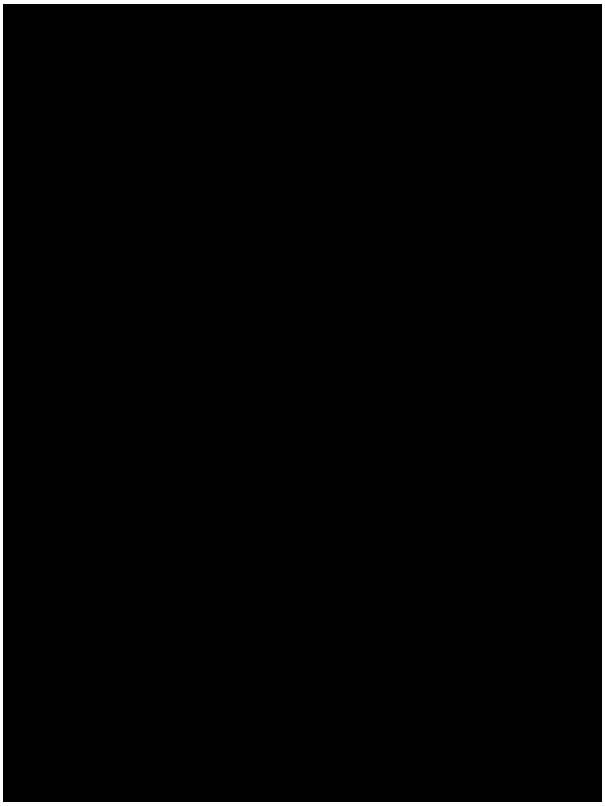

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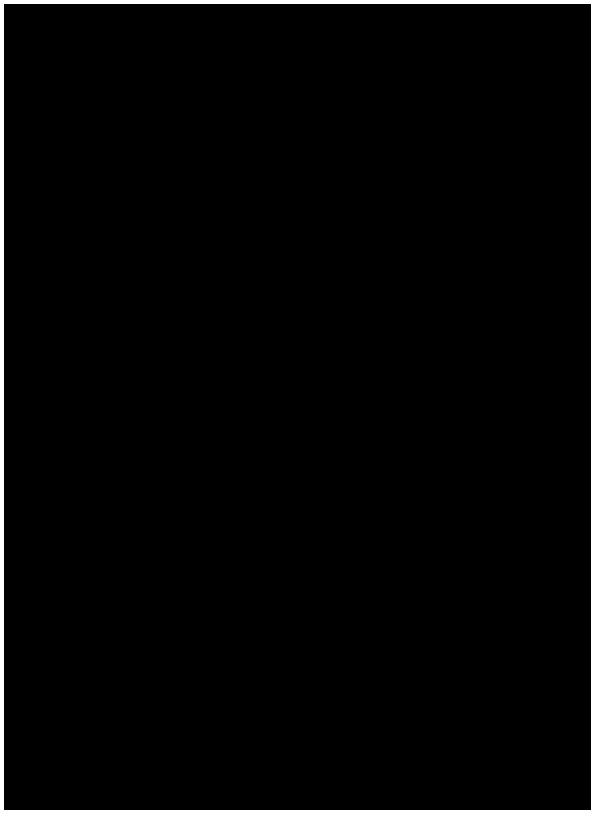

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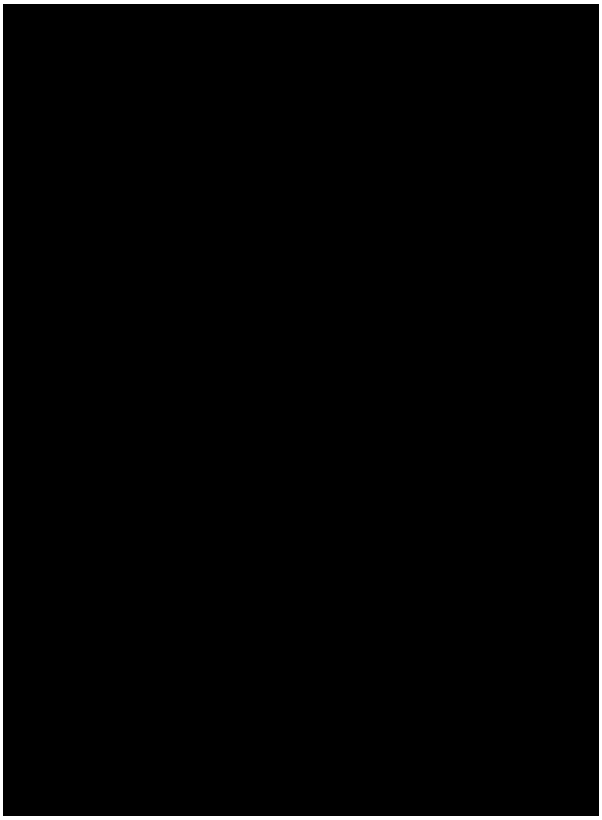

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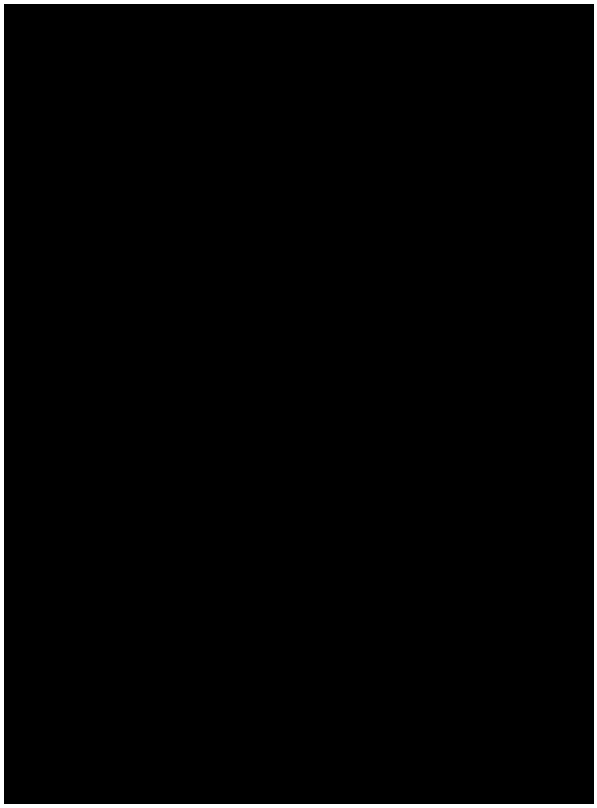

Page 210

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Page 211

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Page 212

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Page 213

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Q. Which a doctor has for controlled substances?
A. In addition to -- in addition to his -- his State Board of Pharmacy license, which, by the way, his DEA registration is contingent upon his license, his State Board.
Q. Right.
A. Okay. So if -- again, I'm

Page 214

not --
Q. I'm going to give you a fact pattern. Because I think right now we're enjoying going afield of each other, and I want to just focus this, okay. I take full responsibility for it.
MR. McDONALD: Just listen to his question. Okay.
BY MR. MIGLIORI:
Q. A doctor who has a prior conviction for drug trafficking who has his license revoked and his DEA registration suspended and reinstated seeks to become a new customer of Henry Schein.
Does Henry Schein, as of 2009, under this new system, do an inquiry of that new customer, of whether or not he or she has had prior convictions for drug-related offenses?
MR. McDONALD: Under your hypothetical, the license has been revoked? That's what you said?
MR. MIGLIORI: And then I

Page 215

said -- and then reinstated.
MR. McDONALD: You said his DEA registration has been suspended and reinstated. So both have been revoked and both have been reinstated?
BY MR. MIGLIORI:
Q. His license revoked and DEA registration suspended and reinstated, referring to both.
Let's say a doctor is in fact convicted of drug trafficking.
A. Okay, okay.
Q. And his licenses are revoked --
A. Revoked.
Q. -- and reinstated.
A. And then reinstated. Okay.
Q. In 2009, does Henry Schein inquire of that doctor of his or her criminal convictions that may be related or informative of whether or not that doctor should be ordering controlled substances?

Page 216

MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: So that would be a verification function. And when they are setting up the account, and I don't want to guess --
MR. McDONALD: Don't guess. You're not here to guess.
THE WITNESS: I'm not going to guess what their --
MR. McDONALD: If you know, tell him. If you don't, tell him that you don't know.
THE WITNESS: I don't know what their practice would be in that hypothetical.
BY MR. MIGLIORI:

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Page 217

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Q. Was it a good idea?
MR. McDONALD: Object to the form.
THE WITNESS: Do I think it's a good idea?
BY MR. MIGLIORI:

Q. Yeah.
A. Absolutely.
Q. Would you have concern as director of regulatory affairs for a doctor who does have a drug trafficking past wanting to buy an order of controlled substances from Henry Schein?
A. You're asking me would I have a concern if a doctor had a drug trafficking violation?
Q. Conviction.
A. Conviction?
Q. Yes.
A. Wanted to buy pharmaceutical, controlled substances?
Q. Yes.
A. That would be concern.
Q. If verifications escalated that new customer inquiry to you and to Sergio Tejeda, that we have a customer here that wants to buy controlled substances from us, but in fact it turns out that over a decade ago, that doctor was convicted of drug trafficking, that

would be something concerning to you, correct?
MR. McDONALD: Object to the form. Improper hypothetical.
BY MR. MIGLIORI:
Q. As director of regulatory affairs at the time?
A. I would be concerned.
Q. But whether or not this was actually implemented going forward, you just -- you just don't know as you sit here today, is that a fair statement?
A. I don't know what verification implemented on all these -- you know, there are lots of enhancements that were made.
MR. McDONALD: Let's take a break. We've been going for a while.
MR. MIGLIORI: Sure.
THE VIDEOGRAPHER: All right. Remove your microphones. The time is 3:10 p.m. Off the record.

(Short break.)
THE VIDEOGRAPHER: We are back on the record. The time is 3:29 p.m.
(Document marked for identification as Exhibit Schein-DiBello-19.)
BY MR. MIGLIORI:

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Page 222

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Page 223

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Page 224

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Page 225

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(Document marked for identification as Exhibit Schein-DiBello-20.)

BY MR. MIGLIORI:

Q. I'll show you Exhibit 20. I'm not going to go too deeply into this

one.

We made reference to the HDMA and a guidance that they put out in 2008. Do you recall the 2008 HDMA guidance on suspicious orders? Suspicious order monitoring and compliance with DEA?

A. Vaguely recall.

Q. And at this time, Henry Schein is an active member of HDMA, correct?

A. Henry Schein is a member of HDMA.

Q. And you attended HDMA conferences yourself?

A. Yes, I did.

Q. And you, in part, relied on HDMA to learn about DEA compliance, correct? Isn't that one of the examples you gave me earlier?

A. We attended conferences and we -- we attended other conferences. Not just HDMA.

We -- we relied on some of

their guidances. They were guidances.

Q. I'm just simply asking you, was this one of the examples of the trade associations where you got on-the-job training for DEA compliance?

A. This was one example. Yes.

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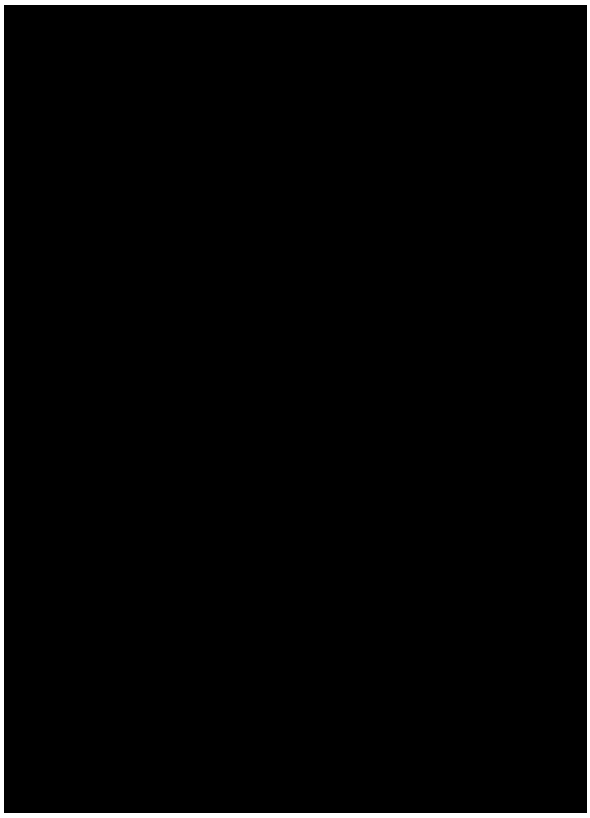
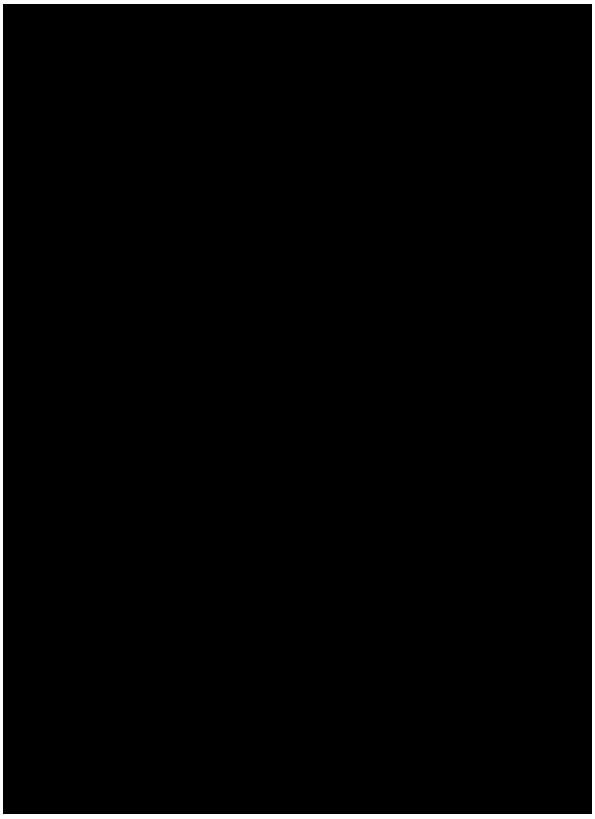
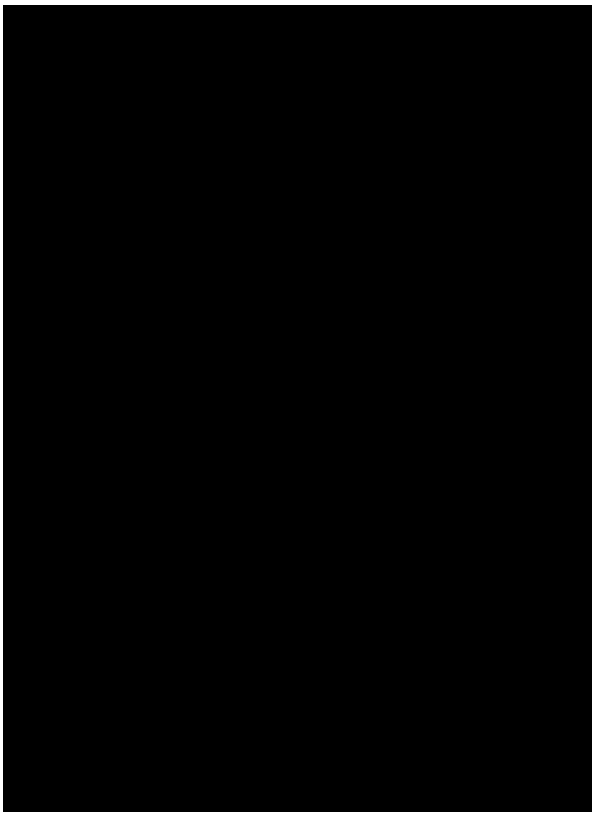
Page 230



Page 231



Page 232



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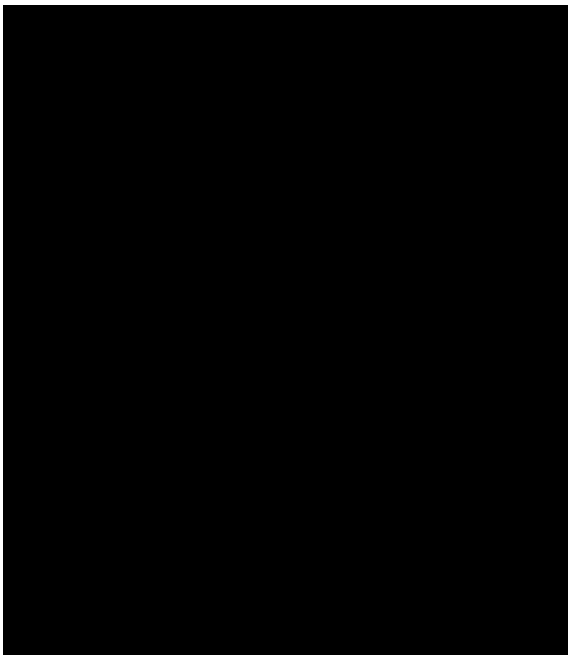

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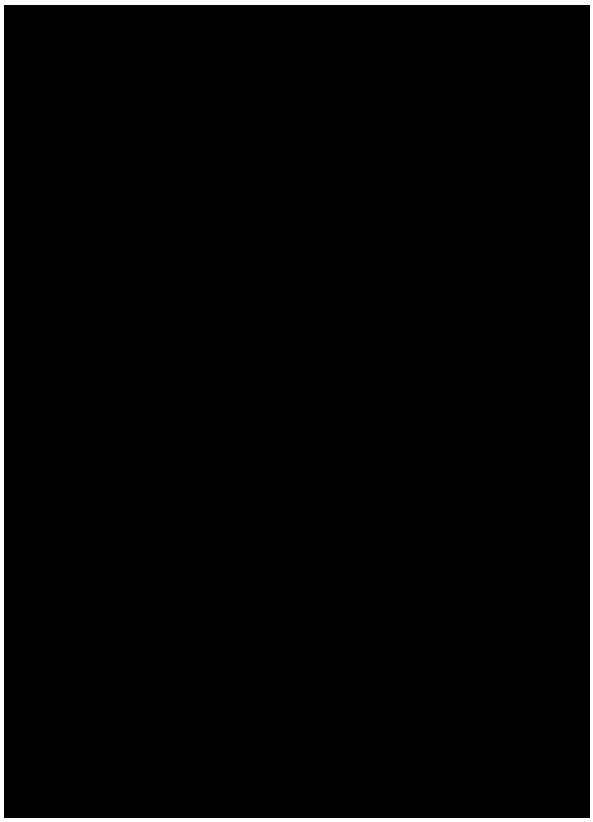
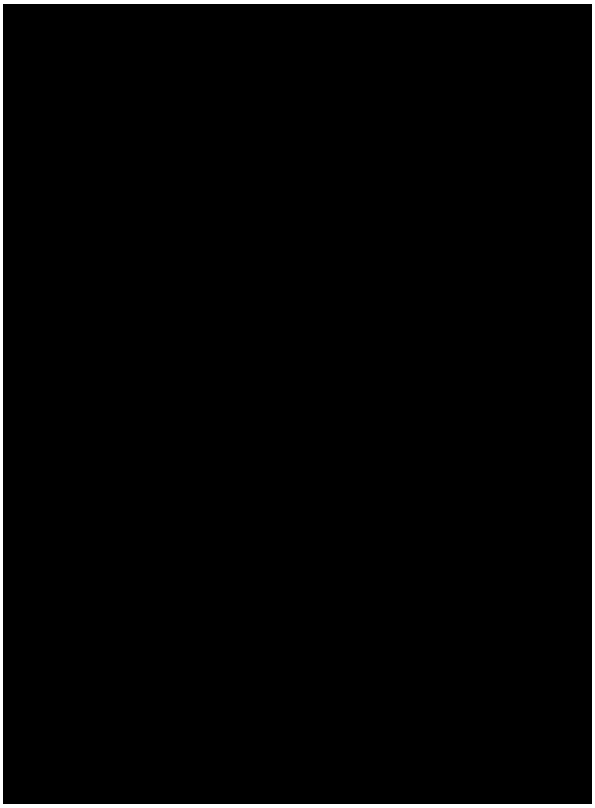
BY MR. MIGLIORI:

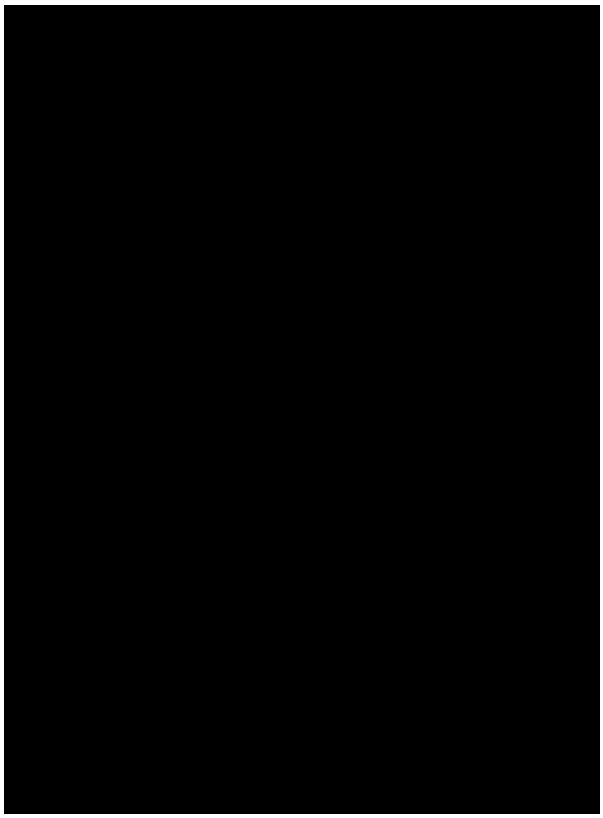
Page 234



Page 236



Page 235



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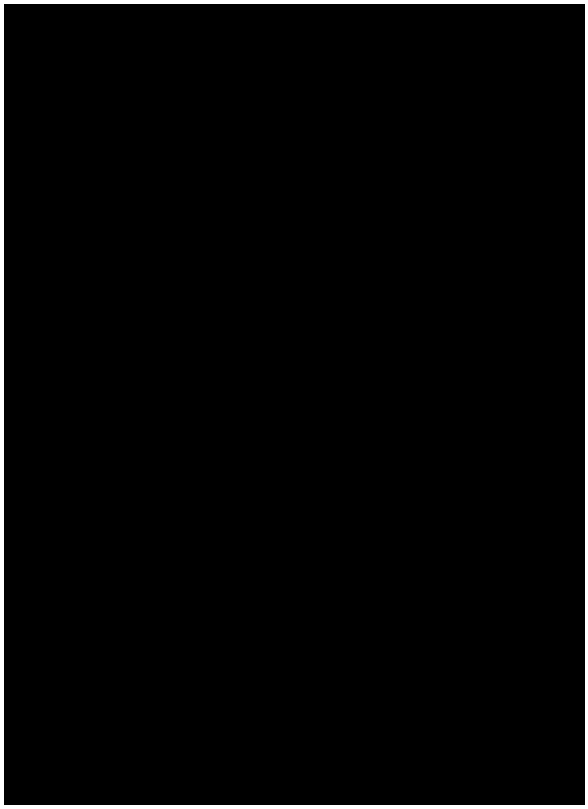

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BY MR. MIGLIORI:

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Page 242

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Page 243

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Page 244

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A. I've never seen this document. And there were meetings that were ongoing throughout the entire and -- and post-implementation process.

Q. Okay.

A. So it was -- again, it was a dynamic evolutionary process that was constantly being enhanced and improved.

Q. You would agree with me that this enhancement and improvement was in coordination with the regulatory affairs department and verifications?

A. It was -- regulatory's role was to work with other departments that would -- that would implement certain enhancements, such as the verifications

Page 245

group and the IT group. And so there were multiple parties working on these enhancements.

Q. Okay. My question was simply, you'll agree with me that two of those parties were verifications and your department, regulatory affairs, correct?

A. Two of those departments, yes.

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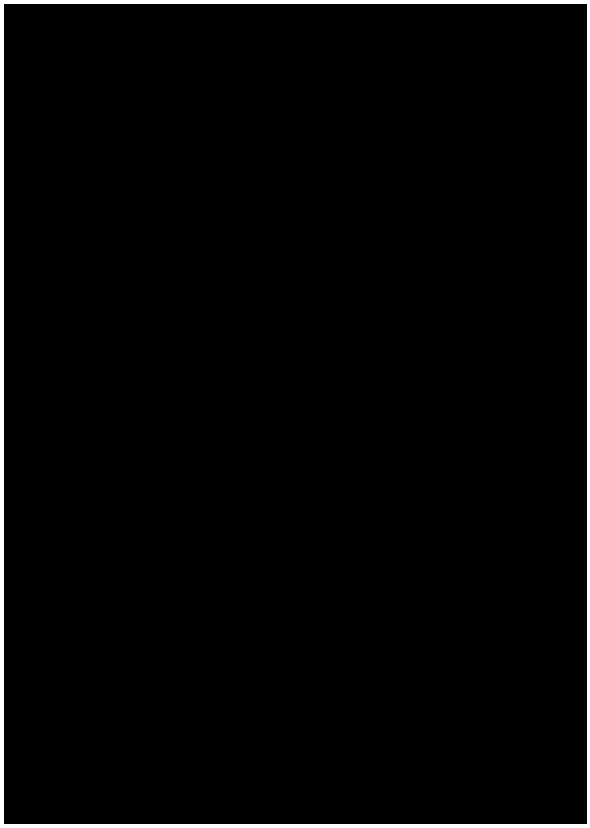
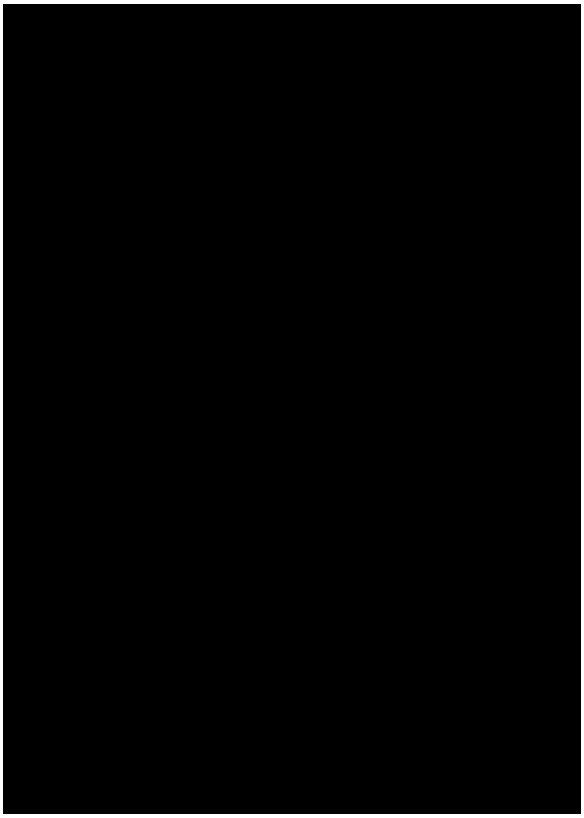
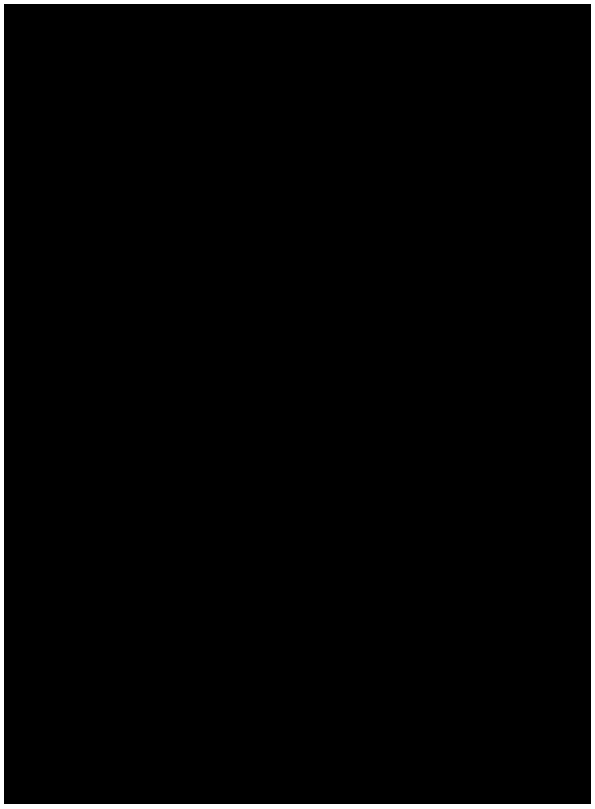
Page 246



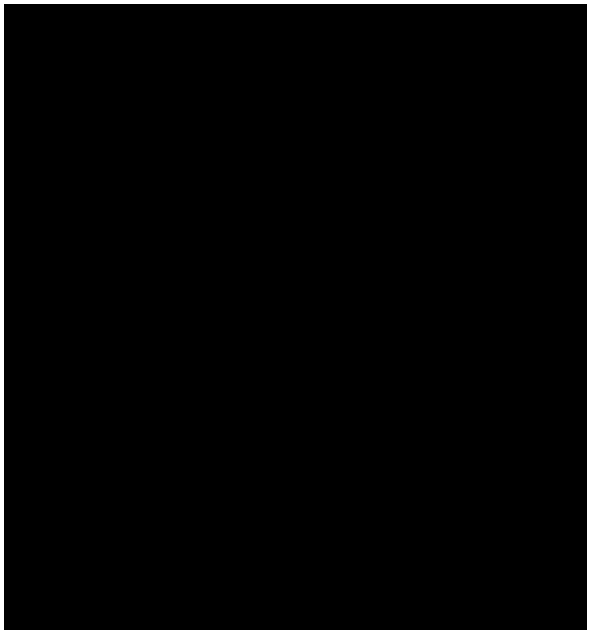
Page 248



Page 247



Page 249



(Document marked for identification as Exhibit Schein-DiBello-23.)

BY MR. MIGLIORI:

Q. I'll show you Exhibit

Page 250

Number 23.

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Page 252

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Page 251

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Page 253

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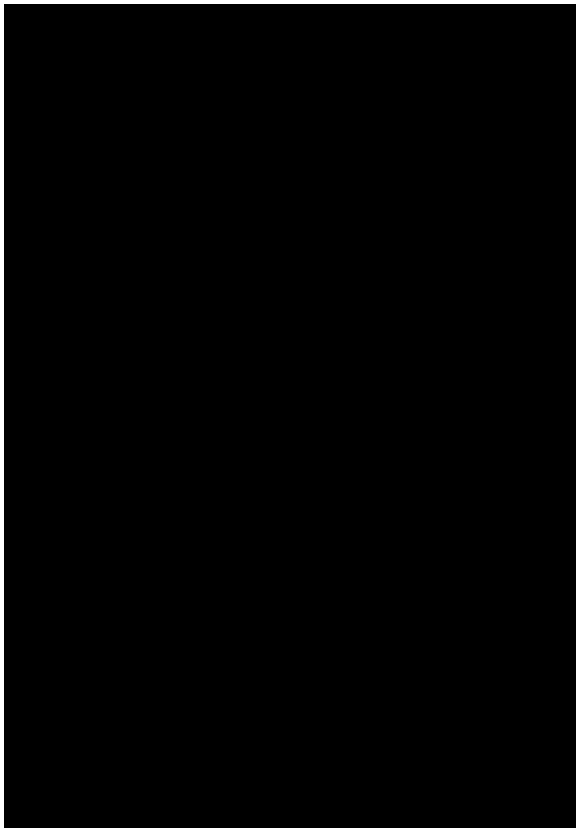
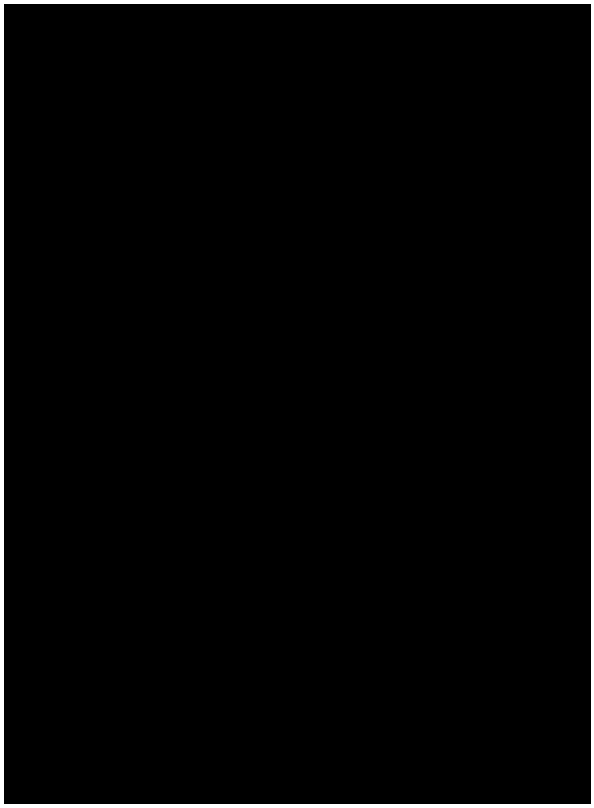
Page 254



Page 256



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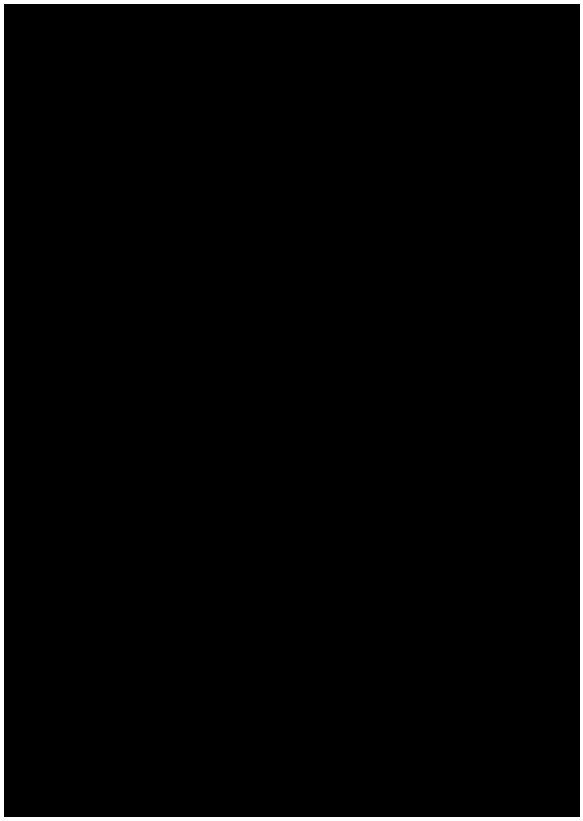
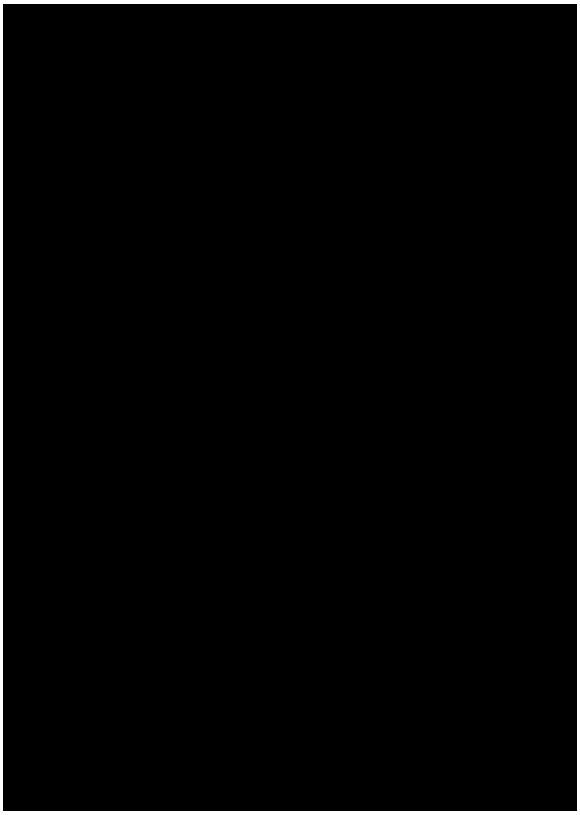
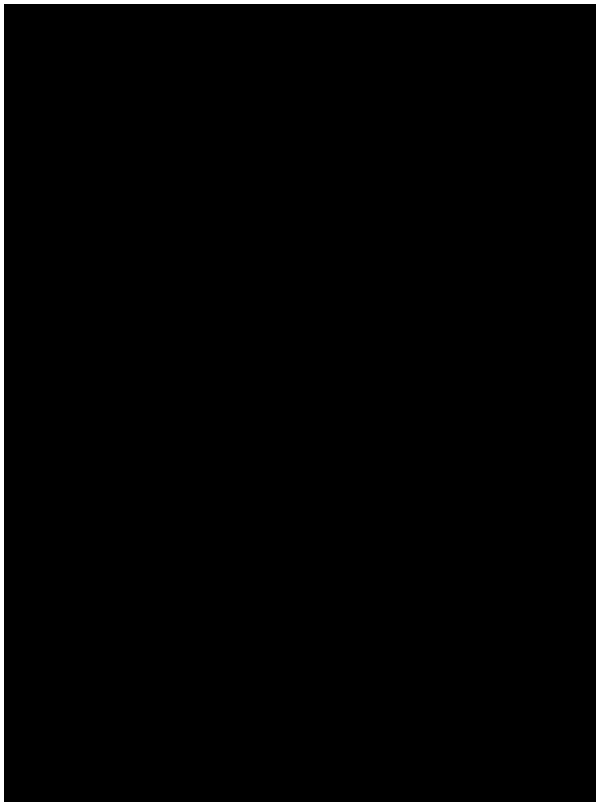


Page 257



Page 258



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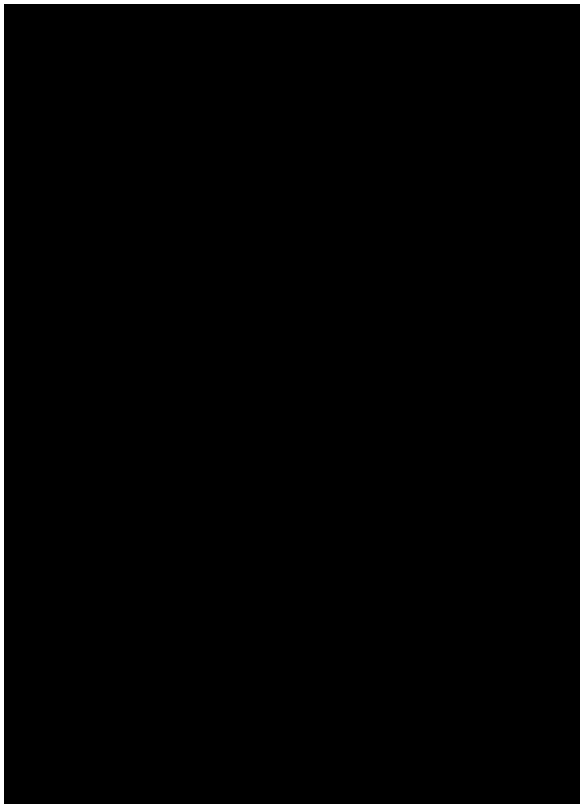
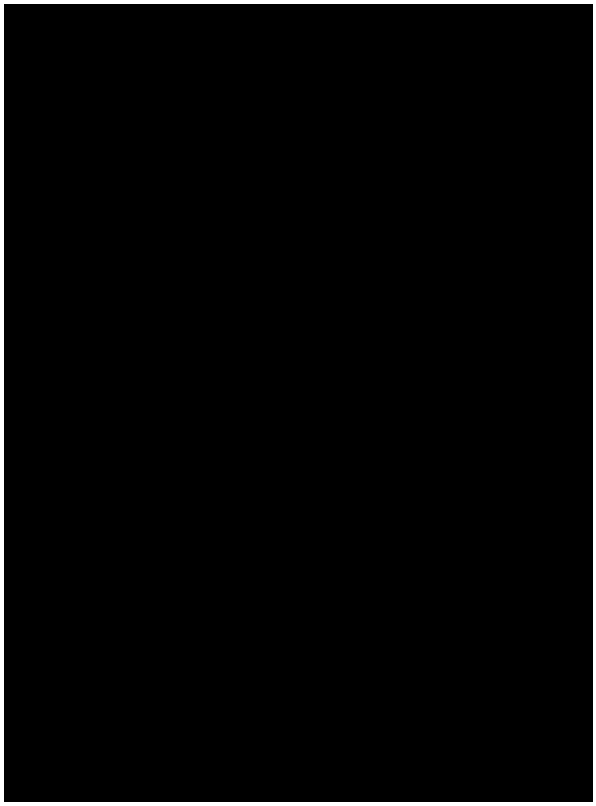


Page 259



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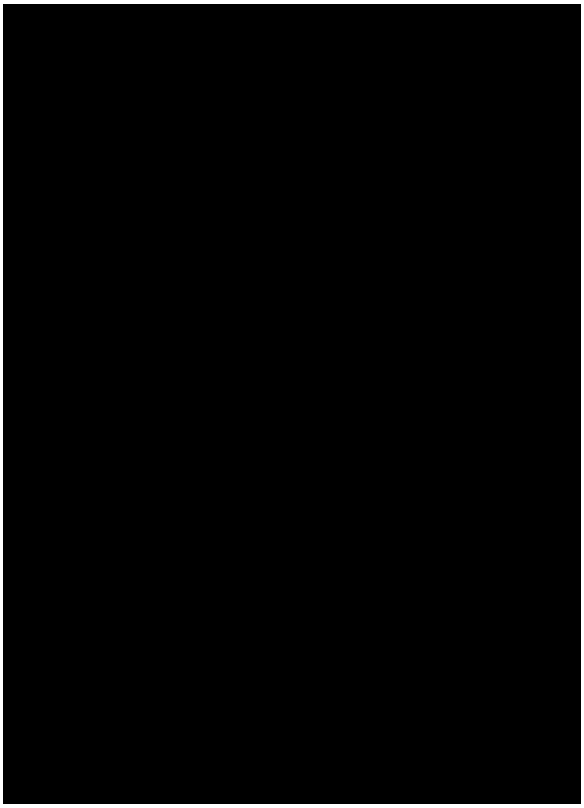

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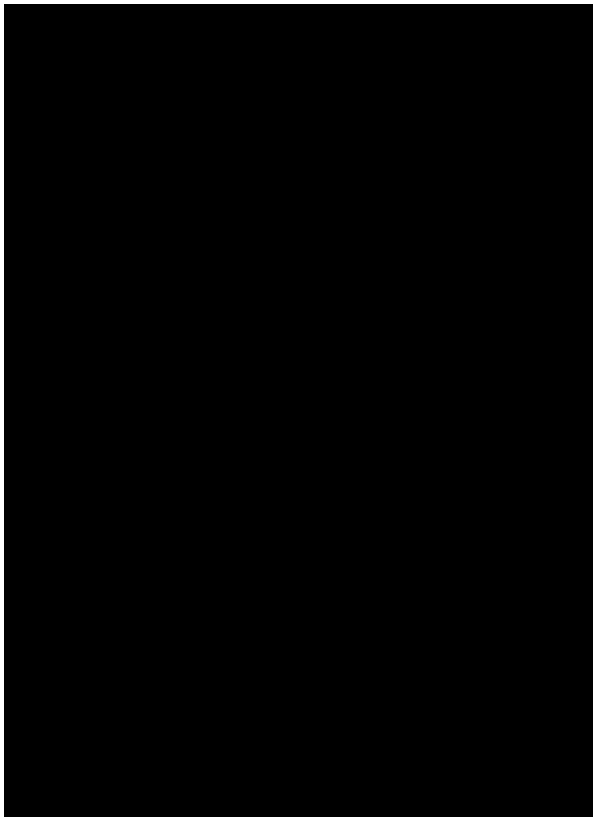

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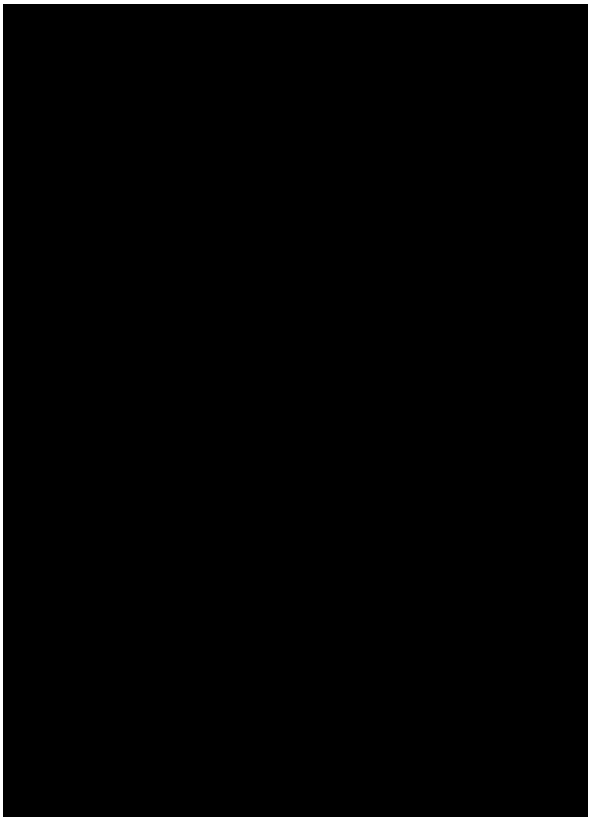

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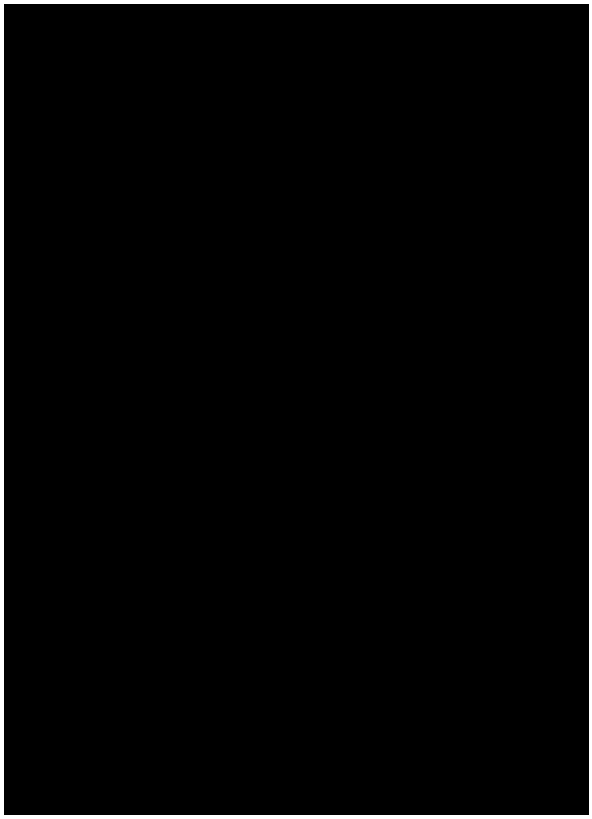

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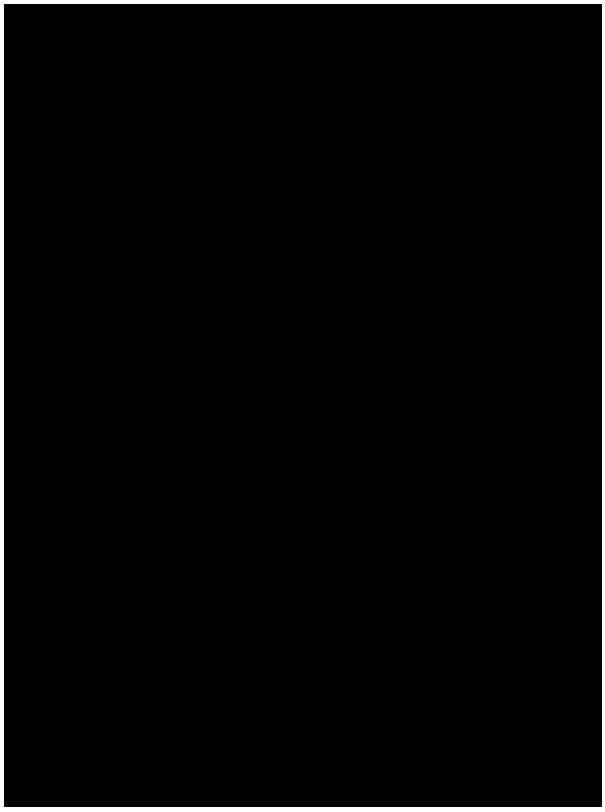
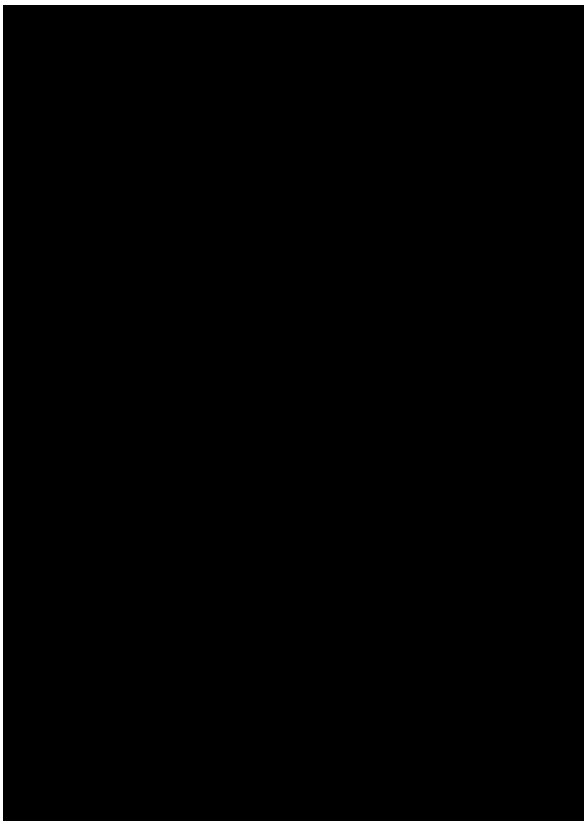


Page 266



Page 267

Q. So in 2011, when an order -- I'll go back to Page 2 for a second. When an order is pended, because of a deviation in size, frequency or pattern, by this procedure the DEA isn't notified immediately as of February of 2011?

A. The order is -- is pended here. It's not deemed to be suspicious.

Q. All right. But what we saw in the early documents that a suspicious order is one that is a deviation in size, frequency, and pattern.

A. Right.

Q. And that once pended, it needs to be reported, as Buzzeo stated in 2005, it needs to be reported

Page 268

immediately, correct?

MR. McDONALD: Object to the form. Mischaracterizes the document.

BY MR. MIGLIORI:

Q. Not -- not at the end of the month, correct?

MR. McDONALD: Object to the form. Mischaracterizes the document and the testimony. That is not what the document said.

THE WITNESS: The order is pended here. That doesn't mean it's suspicious. There's a whole review process here, we just went through.

BY MR. MIGLIORI:

Q. I'm going to -- let me give you a hypothetical so we're not confusing.

If an order is a deviation in size, it is a pended order in Henry Schein's system, correct?

A. If it's a deviation in size.

Page 269

Q. Yes?

A. Yes.

Q. An order that is a deviation in size, by definition under the CSA, is suspicious, correct?

MR. McDONALD: Object to the form.

THE WITNESS: Not necessarily.

BY MR. MIGLIORI:

Q. All right. Well, you actually had a document where you said exactly that, that we just referred to earlier.

You're saying that a deviation in size is not a suspicious order?

A. Potential, potentially. Potential. It could be. That's the review process that we're doing here.

Q. So in Schein's system, in February of 2011, Schein is not reporting immediately a deviation in size of order from prior purchasing history to the DEA

Page 270

upon discovery. Is that true?
A. We were reporting suspicious orders.
Our definition of a suspicious order, after the review is conducted and deemed to be suspicious, that's when it was reported immediately.
Q. So this flowchart is accurate, that you would not have told DEA about this until you got to this last step here of it being --
A. Deemed suspicious.

[redacted]

Page 271

[redacted]

(Document marked for identification as Exhibit Schein-DiBello-24.)
BY MR. MIGLIORI:

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Page 272

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Page 273

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Page 274

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Page 275

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Q. June of 2012, you haven't left -- you haven't left Schein yet, correct?

A. That's correct.

Q. You left in September?

A. October.

(Document marked for identification as Exhibit Schein-DiBello-25.)

BY MR. MIGLIORI:

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Page 276

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Q. Okay. But this is something you would have received --

A. I would have received -- I would have received it.

Q. Were you still there in October 15, 2012?

A. 2012, October 15th. I had

Page 277

resigned. That was my last week, actually. I think my last -- I'm not sure. I might have left before the 15th. It was right about that time. I don't remember the actual resignation date. But it was -- I might have left by then, or it was my last week. Yeah, I gave three weeks' notice.

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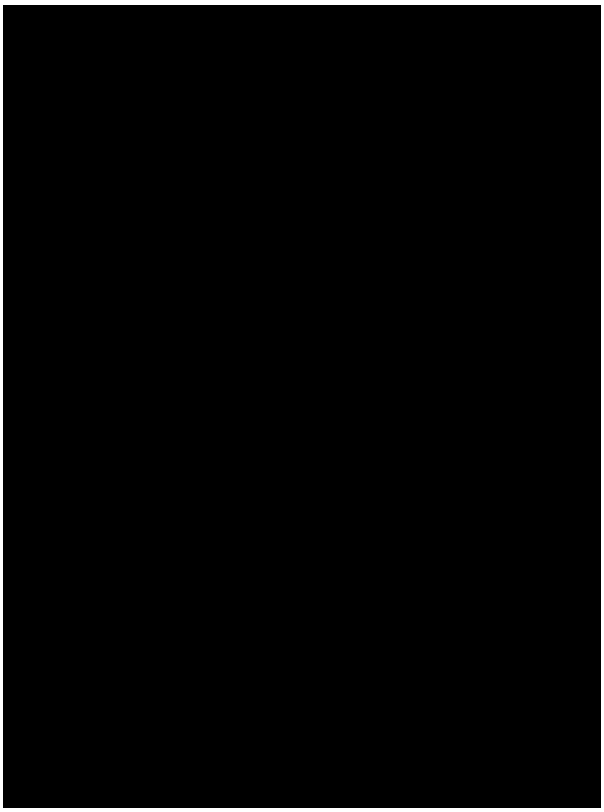
Page 278



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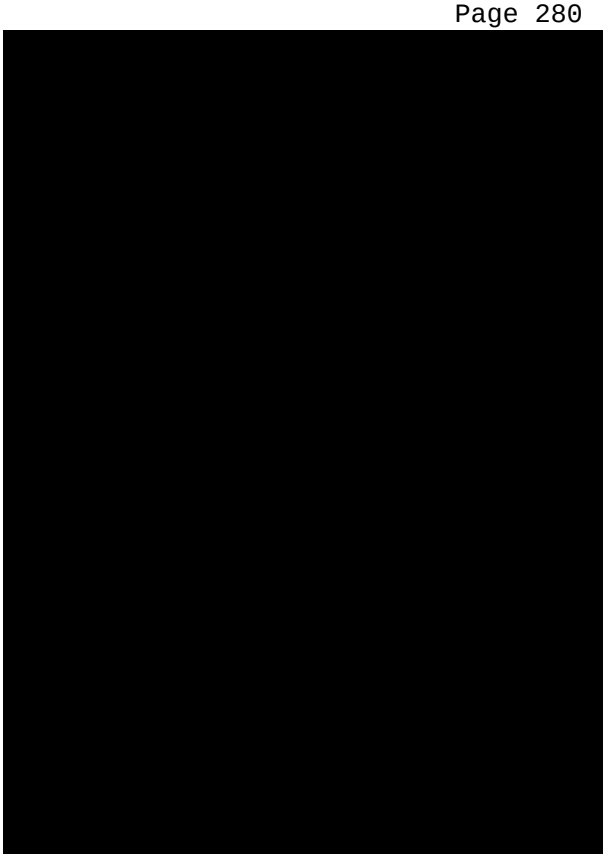

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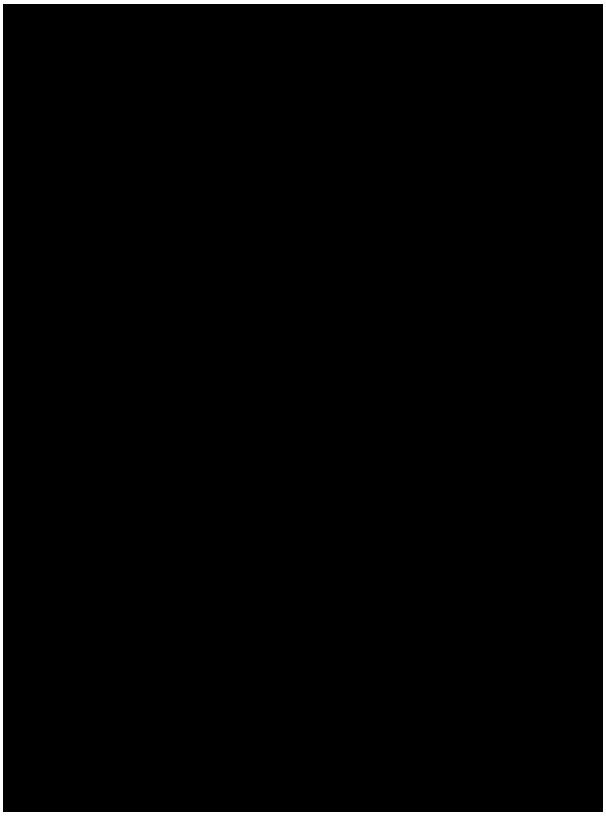

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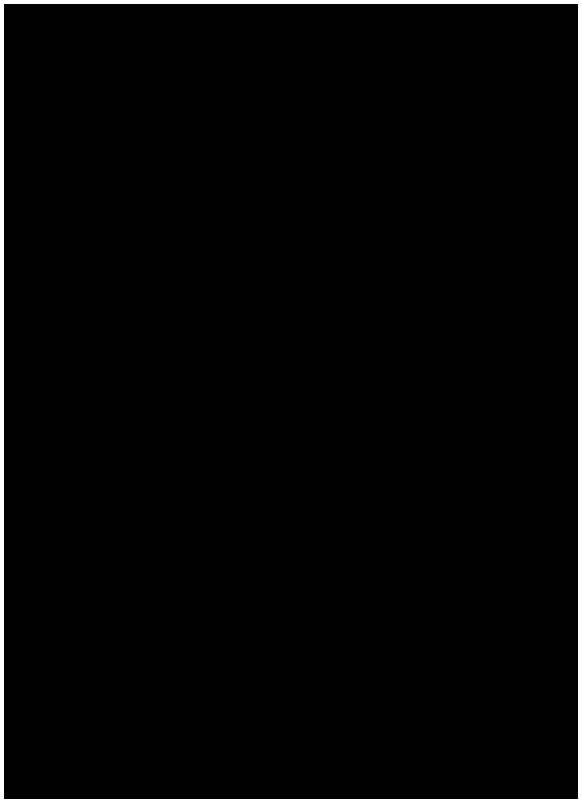

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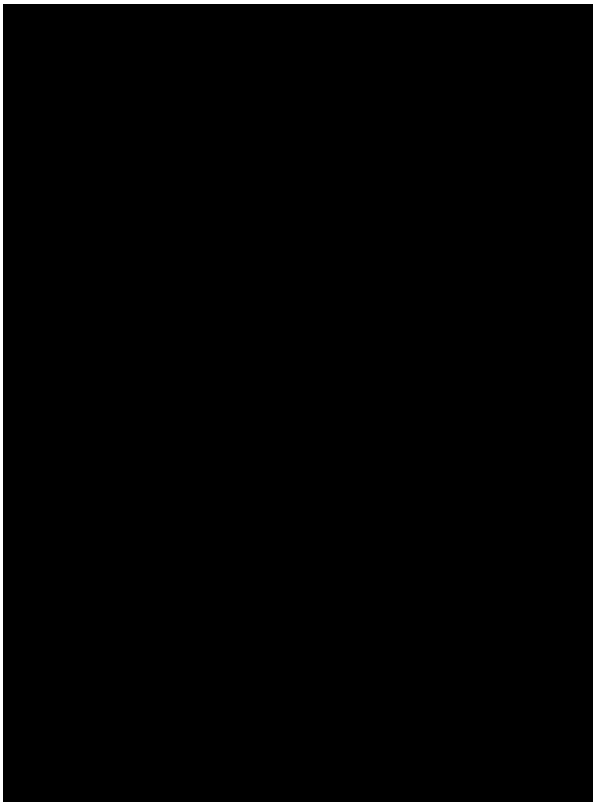

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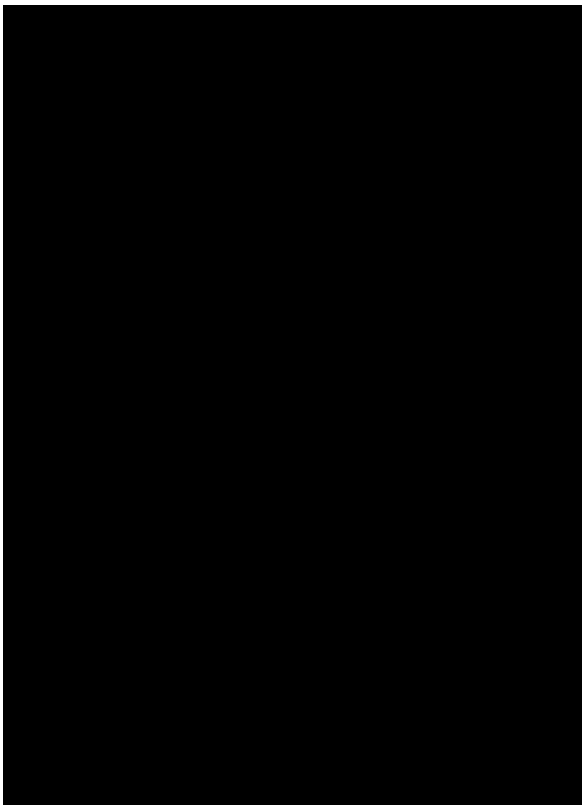

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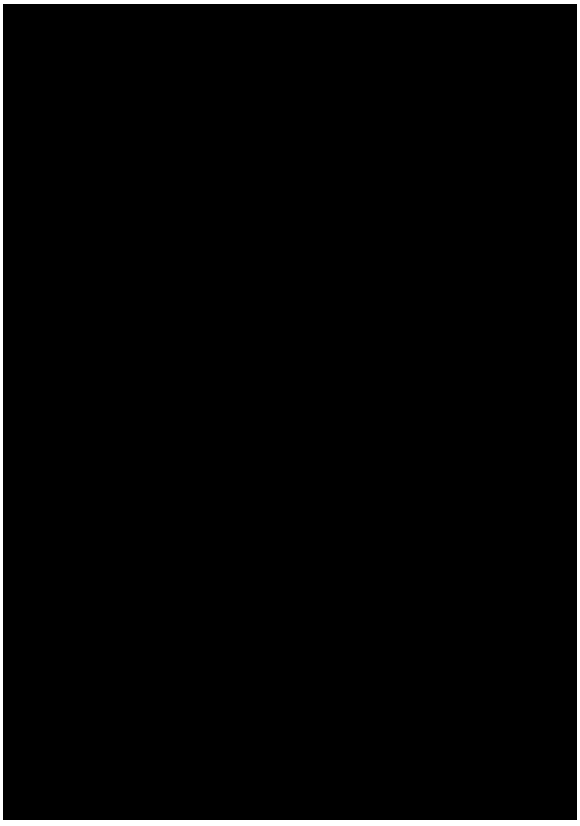

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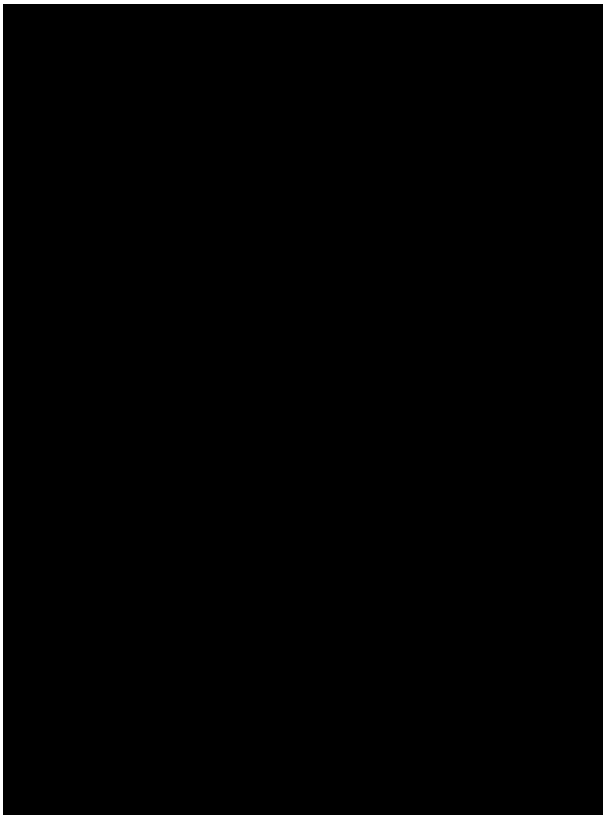

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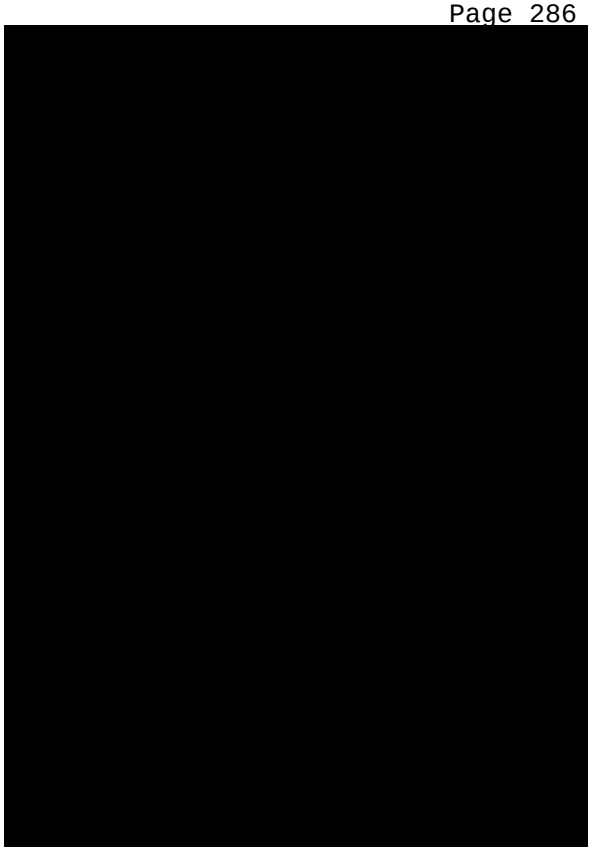

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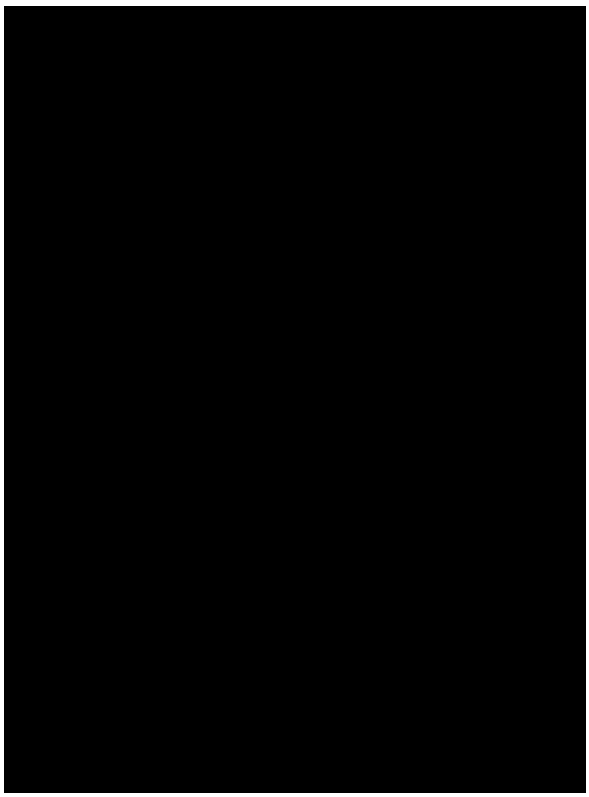
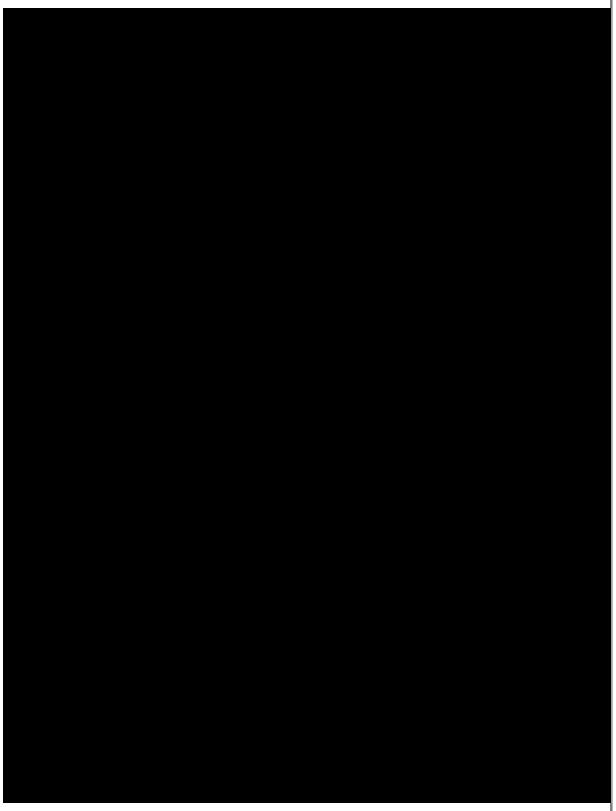
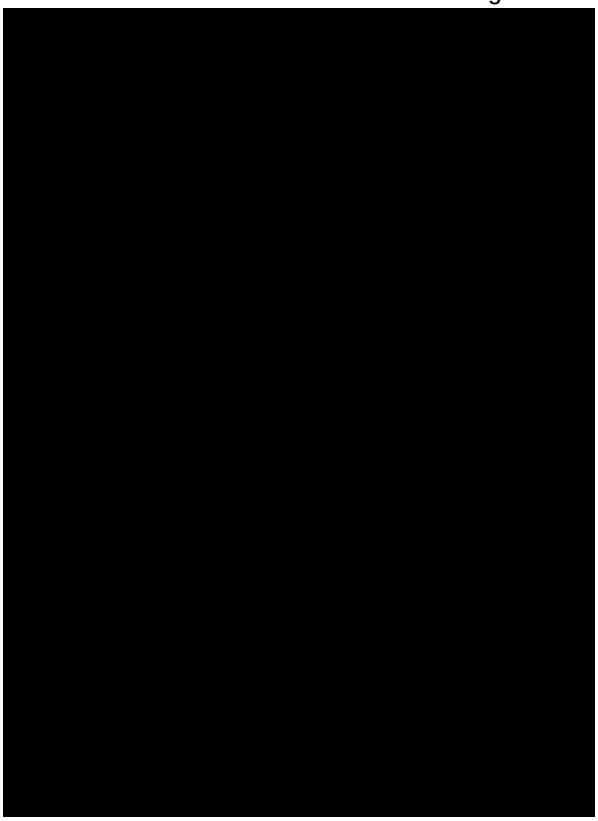


Page 287



Page 289



Page 290

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Page 291

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Page 292

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BY MR. MIGLIORI:
Q. Including the customer

Page 293

questionnaire, correct?
MR. McDONALD: Object to the form.
Object to the form.
THE WITNESS: That's one way of documenting their review of this account.
BY MR. MIGLIORI:
Q. In 2012, the customer questionnaire was required for all customers, correct?
A. I don't recall when it went into place. And -- and if there were exceptions or other methods of verifying the doctors' status.
(Document marked for identification as Exhibit Schein-DiBello-28.)
BY MR. MIGLIORI:

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Page 294

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Page 295

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Page 296

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MR. MIGLIORI: Why don't we take a break and I'll look at what I got and we'll wrap up.

THE VIDEOGRAPHER: Stand by please. The time is 4:44 p.m. Off the record.

(Short break.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:54 p.m.

BY MR. MIGLIORI:

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Page 297

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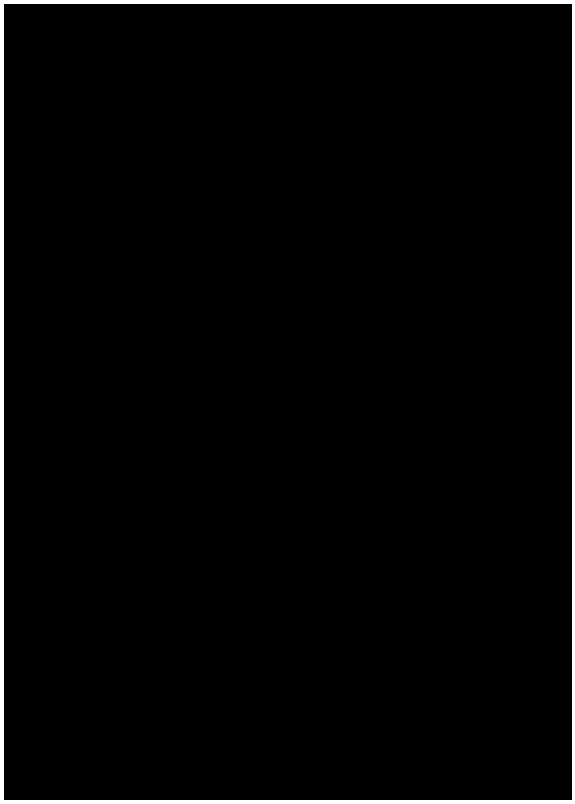
Page 298



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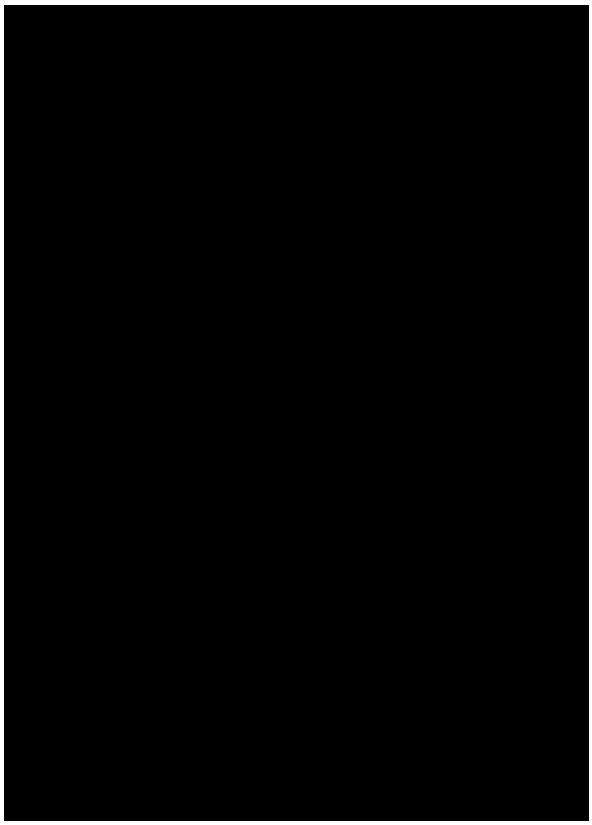
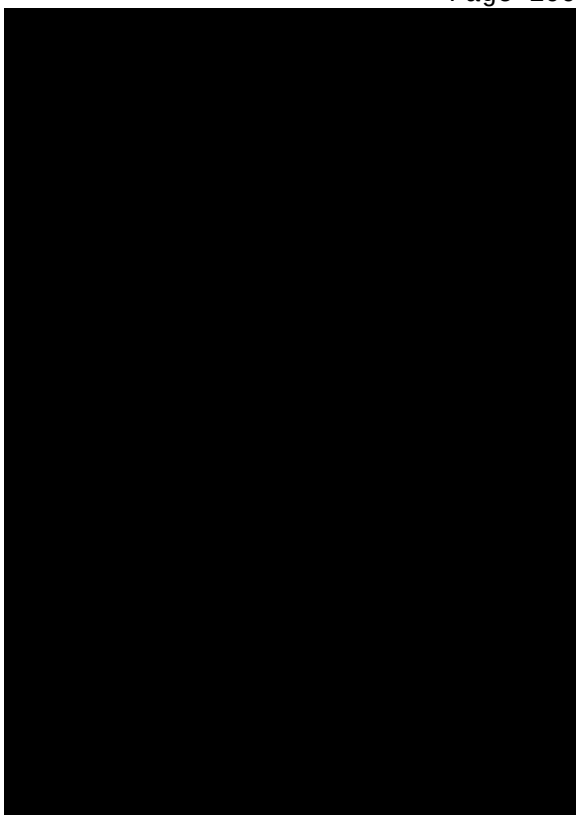
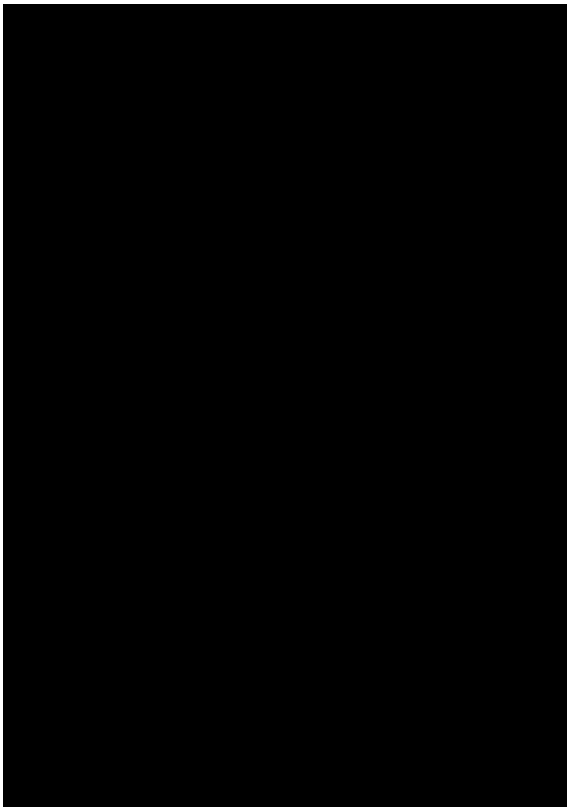


Page 299



Page 301



Page 302

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Page 303

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BY MR. MIGLIORI:

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Page 304

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Page 305

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Page 306

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Page 307

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(Document marked for identification as Exhibit Schein-DiBello-31.)

BY MR. MIGLIORI:

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Page 308

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Page 309

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Page 310

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Page 311

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Page 313

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(Document marked for identification as Exhibit Schein-DiBello-32.)

BY MR. MIGLIORI:

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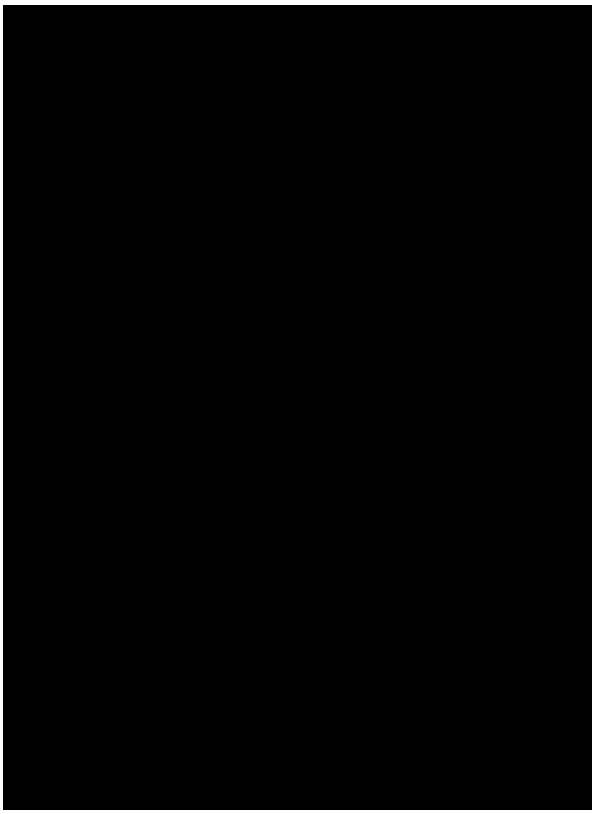
Page 314



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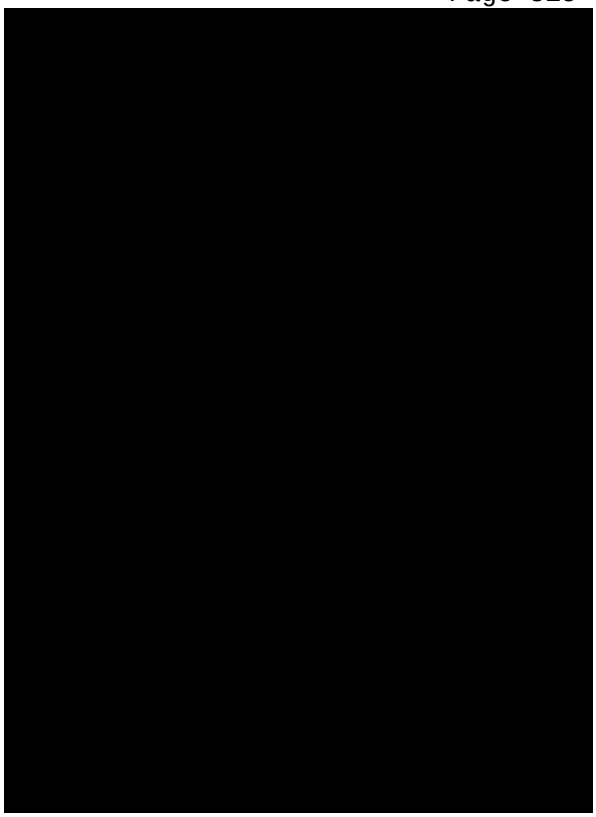

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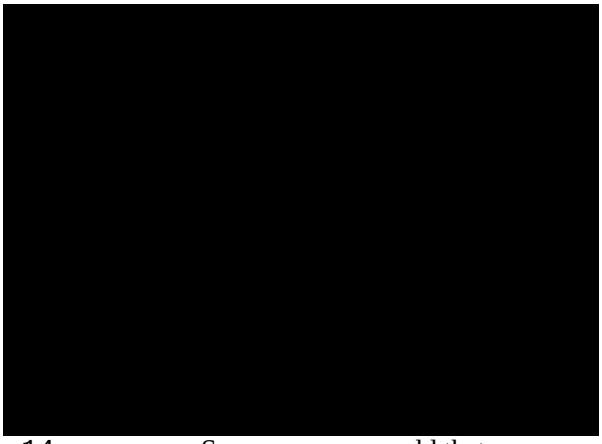

So were you -- would that have been a function of regulatory affairs to make sure that Henry Schein was in compliance with Ohio reporting requirements under the prescription monitoring program, the law in the state of Ohio for those two years?

A. It sounds like a verification report.

Q. So reporting of transactions of sale of controlled substances from

Page 317

Henry Schein from 2010 to 2012 was the function of the verifications department and not the regulatory affairs department?

A. That's what it sounds like, yeah.

Q. And yet this letter is being written from the regulatory affairs department, correct?

A. That's correct, because regulatory would interact with the agency. But the actual reporting, just like the ARCOS and other reports, are verification functions.

Q. Okay. And you agree with me that reporting is an essential part, is an integral report of the effective detection and prevention of diversion, both at the state and federal levels, correct?

MR. McDONALD: Object to form.

THE WITNESS: I would agree.

BY MR. MIGLIORI:

Q. Go ahead.
A. I would agree.
MR. MIGLIORI: Last document. And we'll get your lawyer out of here.
MR. McDONALD: I actually need to get on a call. I'll pass it on.
MR. MIGLIORI: I won't ask anything objectionable.
This is the last document.
BY MR. MIGLIORI:
Q. We got a little late start with the 10:30 time. I'm trying to get us out of here on time.
(Document marked for identification as Exhibit Schein-DiBello-33.)
BY MR. MIGLIORI:
Q. Exhibit Number 33. Jeff Peacock was your successor?
A. Correct.

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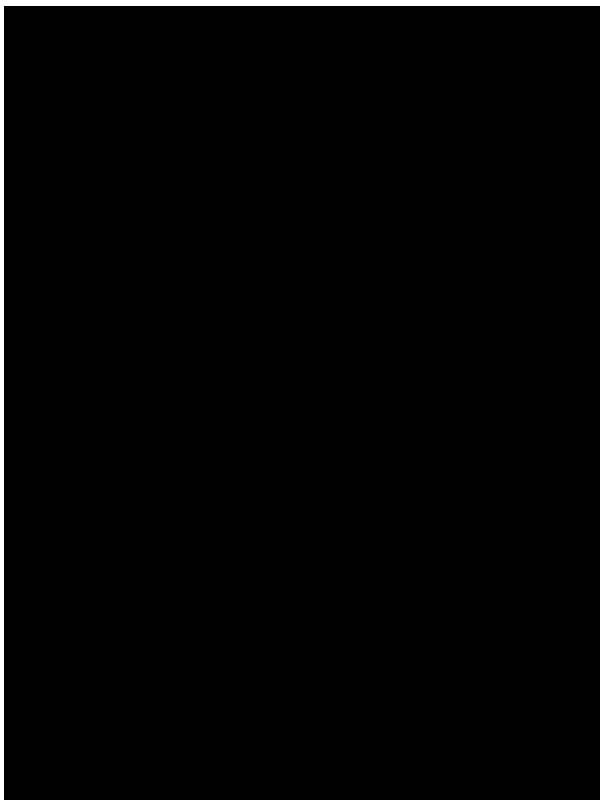
Page 322



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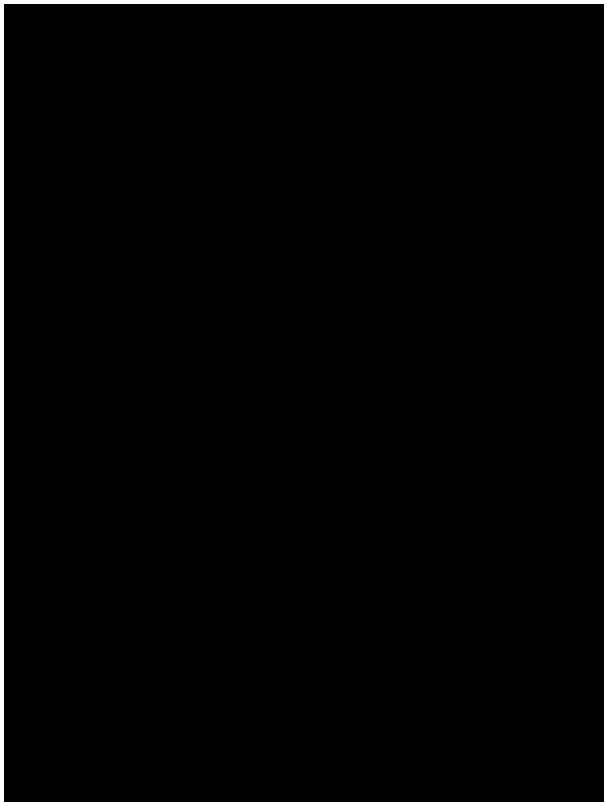

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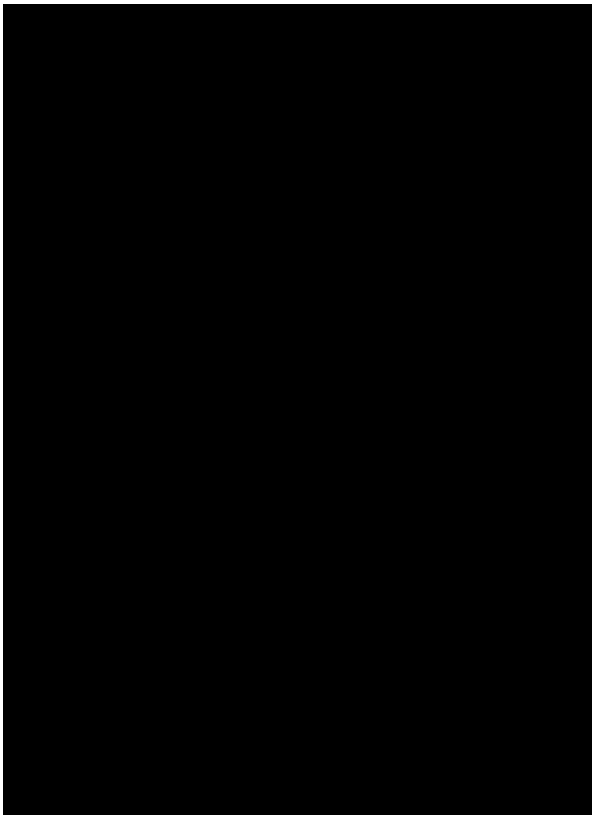

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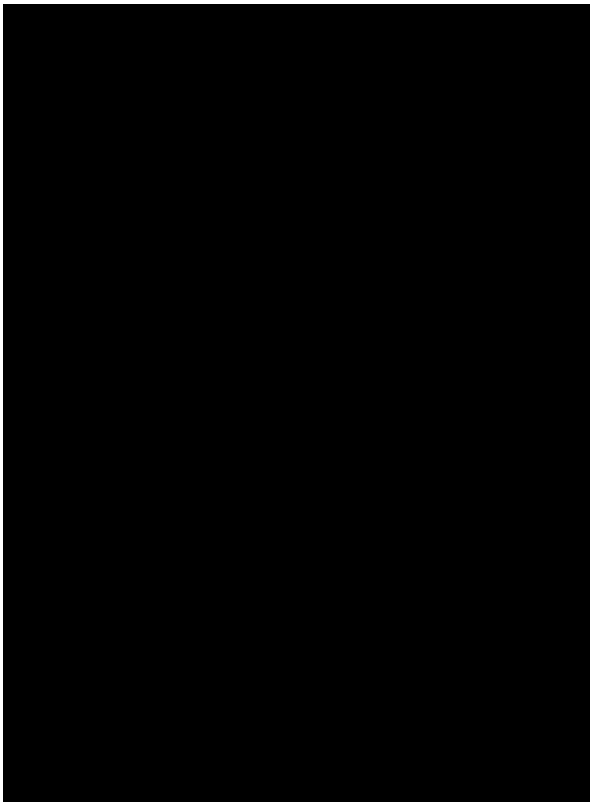

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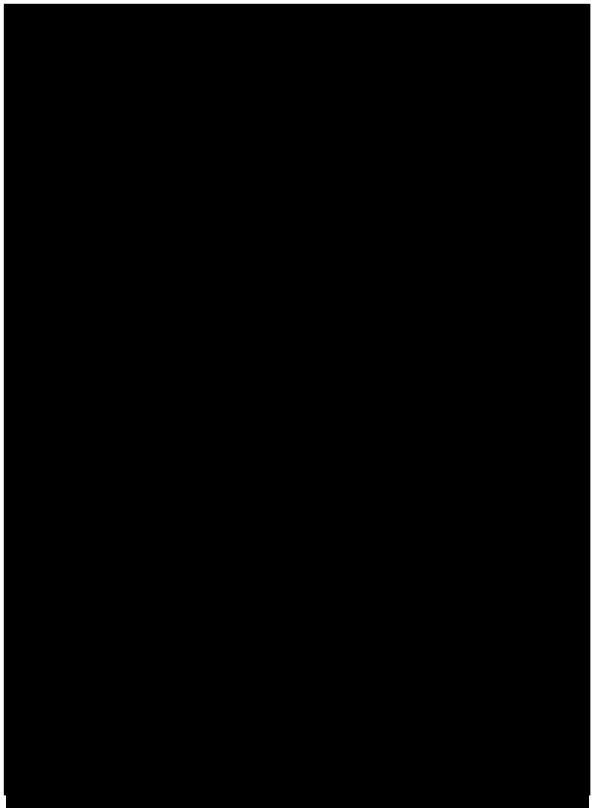

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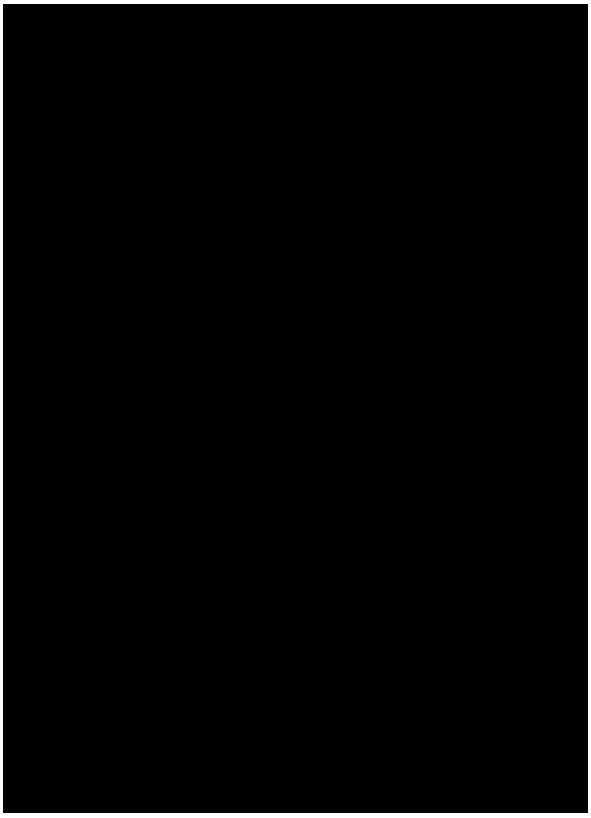

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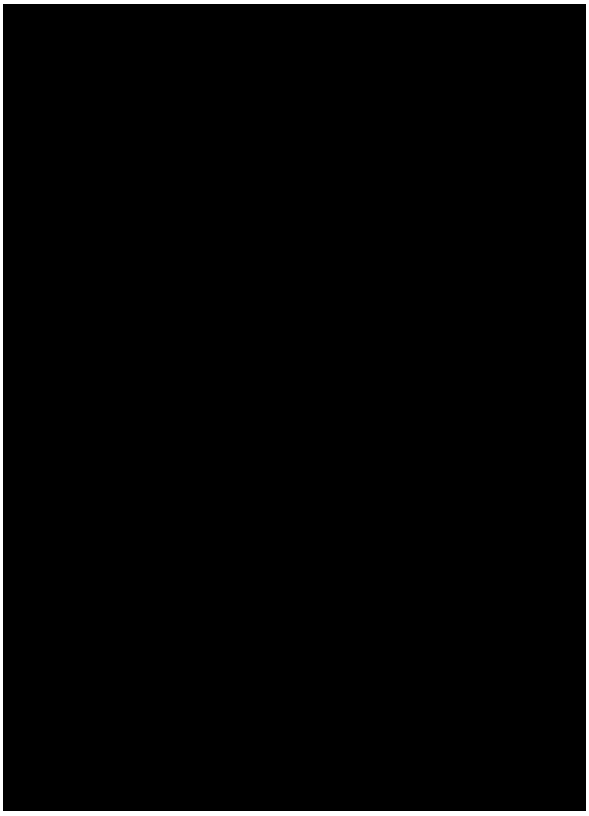

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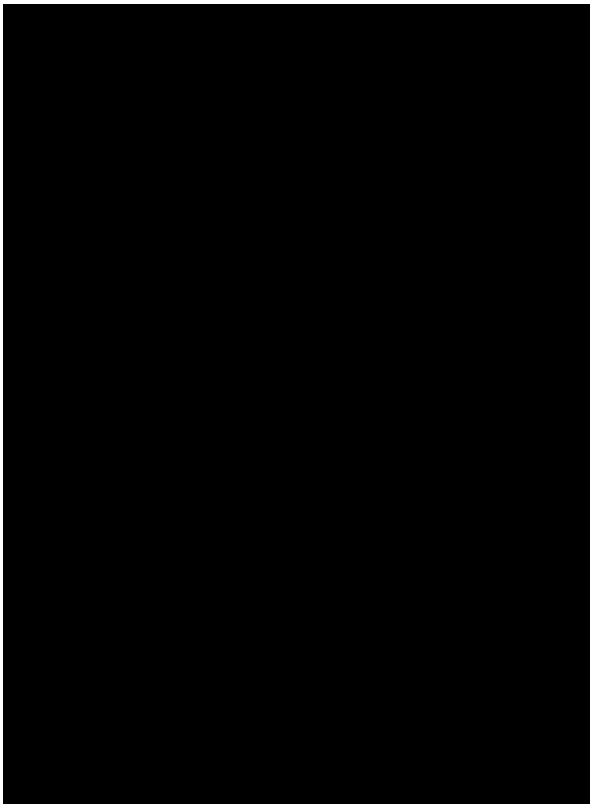

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MR. MIGLIORI: Sir, I appreciate your time. I think that's all I have. I appreciate it.

THE WITNESS: Thank you.

MR. JONES: We'll reserve our questions.

THE VIDEOGRAPHER: Stand by please. This marks the end of today's deposition. The time is 5:28 p.m. Off the record.

(Excused.)

(Deposition concluded at approximately 5:28 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, MICHAEL DiBELLO, have the opportunity to read and sign the deposition transcript.

_____

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: February 22, 2019

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 337, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

MICHAEL DiBELLO DATE

Subscribed and sworn to before me this

_____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

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____ ____ _____

____ ____ _____

____ ____ _____

A

a.m 1:17 13:6 19:16 88:4
ability 148:22 301:7
able 22:17 64:23 100:23 111:19 113:17 115:6 124:19 149:2,5 181:1,8 203:20 203:23 204:2 251:1
Abreu 20:2 52:5 73:16 286:11 307:8 308:12 308:21 309:8 311:22 312:9
Absolutely 170:15 218:2
abuse 92:9,23 165:19 171:12 172:1,6,10,16 173:5,6 230:1
abused 278:3
accept 153:9,11 165:22 230:8 231:9,14
acceptable 106:11 203:18 230:15 256:13
accepted 92:15 92:17 221:4
accepting 291:22
access 105:8 203:20 242:15 242:20
account 8:14 133:6 191:23 192:12,14 193:6 195:22 195:24 198:10 198:15,23 199:2 208:5,21 209:1 216:6 221:18 237:24 243:18,21 244:1 251:8 260:5 263:2,9 263:14,21 273:1 279:17 280:8,19 283:8 287:17 288:7 288:10 289:16 291:7 293:7 300:9 301:10 301:11 312:2 312:19,20 313:1,13 324:23 326:23 329:4,13 330:1 330:16
accounted 32:5 321:16
accounting 328:10,15
accounts 75:7 75:14,23 76:3 79:7 133:9 155:9 192:2 211:6 217:15 221:15 222:1 222:19 231:2 237:24 243:1,4 243:10 245:13 272:4,8 273:21 288:14 326:6 327:19
accredited 43:15 43:16
accurate 67:1 81:12 270:9 323:5 334:20
accused 291:19
Aceto 5:18 15:24 16:1,2,7 16:10,15,18,22 16:24 26:5,8 57:5
acknowledge 211:21
acknowledging 202:2
ACKNOWLE... 336:2
acquired 47:12 194:1,19 195:10
acquisitions 47:13
act 48:3 49:14 68:5 70:16 89:14,24 90:1 90:15 91:1,10 130:10 132:13 132:21 142:22 158:7,13 159:9 174:19 176:8 204:24 276:7 316:10
action 10:17 259:15 305:1 305:19 324:14
actions 202:12 212:3 221:9 321:2
active 178:21 180:1 226:10 298:16 321:13
actively 136:8 242:4 246:24 247:6
activities 50:19 82:2
activity 60:18 103:2 131:16
actual 22:2 83:10 156:4 228:2 277:5 286:22 317:12
adaptable 232:12
add 166:15 167:5,11 171:14
added 140:8 156:21 167:3
addition 43:23 129:9 213:18 213:19
additional 161:21 162:2 221:9 225:8,11 225:18 232:14 257:10 330:14 330:16
address 15:17 189:5,24
addressed 250:4
addresses 200:23
addressing 221:8
adequate 205:21 243:6 247:20
adjusted 325:1
adjustment 190:24
adjustments 325:7
administer 13:17
Administering 297:12
administration 34:10 158:18
administrative 45:18,19
administrator 165:8 171:7 276:13
adopted 223:1 224:9,14
adopting 223:5
advised 62:20 108:16 143:5
advisory 41:8
affairs 17:2 21:14 22:12 26:18 36:1,2,8 36:10,17 39:1 41:8 42:3,11 42:16 43:19 44:9 50:17 51:2,22 52:15 52:19 54:5,9 57:22 58:23 60:8 61:8,15 61:21 62:24 86:6 88:17,22 89:5,12 90:24 91:9,19 92:10 92:13,21 93:4 93:13 94:1 95:11,16,20,24 96:7,14,24 100:9 103:7 106:3 116:21 129:20 130:1 138:4,7,10 146:18 165:12 173:22 175:18 185:10,16,22 201:22 203:10 204:18 218:4 219:7 229:21 232:23 234:13 237:17 244:19 245:7 248:20 260:22 267:3 271:24 275:23 288:2 290:18 292:14 294:4 302:20 305:24 307:13 314:2 315:22 316:16 317:3,8 320:2 320:3 321:5 322:10 323:16 323:24 325:15 328:9,16,23 330:9,10,21 331:4
affairs/verific... 319:1
affect 202:13,21 212:4 221:13
afield 214:4
agencies 257:12 260:10 261:4

agency 258:17 259:6 317:12
agent 62:17 299:24
aggressive 129:8
aggressively 242:5
ago 18:1,18 19:2 218:23
agree 76:6 83:13 84:18,20 113:14 122:2 122:10,18 123:9 124:10 136:2 141:17 141:19 144:24 145:6,8,21 146:5,22,24 147:23 149:10 150:4,21 151:19 152:9 153:24 154:9 155:19 156:1,2 156:12,13,13 157:4 159:19 160:5 161:1,5 161:13 162:18 166:5,11 171:23 175:2 177:12 178:7 179:3,9 180:21 180:22,23 182:17 185:17 187:2 194:11 200:2 204:16 205:18 206:1,3 209:7 212:15 212:20 213:1,2 227:21,23 228:4,19 229:10 230:10 231:19 232:3 233:1 236:8,18 238:2 239:2 244:2,17 245:5 248:14 249:1 260:12 271:19 280:7,19 281:21 283:12 287:3,16 290:1 290:16 292:12 296:5 298:15 298:24 299:3 300:12 313:3 317:15,23 318:2
agreed 110:20 114:20 124:6 200:10
agreement 243:23 244:4,7 305:13,14
agricultural 16:6
ahead 301:5 318:1
Al 60:1
alarming 295:18
algorithms 85:6
all-inclusive 175:10
allowed 329:1
allows 288:11
alternative 224:10
alternatives 222:10
Altogether 185:14
American 67:6 92:1
AmerisourceB... 2:22
amount 221:24 278:15
amounts 291:20
amplified 241:18
analysis 154:22 176:14 283:19 285:21
and/or 84:19 320:22 325:2 333:21
Andy 46:19 47:5 47:21,22,24 109:19 126:5,8
Angeles 3:20
animal 67:13
annual 6:10 66:2,7 117:16 117:20 118:2
anomalies 71:16
answer 12:5 14:19,22,23 15:10 25:6 63:23
answered 63:14 81:22 263:24
answering 63:12 153:17
answers 14:16 336:8
anticipate 197:5
anticipated 199:23
anticipates 194:6
anybody 58:11
anymore 45:2
anyway 50:2
API 331:7
apologize 28:8
apparent 39:19
apparently 118:13 312:4
appear 247:24 287:16 304:13 304:22
appearances 2:1 3:1,7 4:1 13:14
appeared 304:19
appearing 304:23
appears 55:11 56:20 125:20 135:11 169:1 192:14 195:24 322:16
applicable 154:14
applied 55:11,13
APPLIES 1:7
apply 169:3 333:19
appreciate 91:18 92:9,12 92:20 93:3 131:5 134:7,18 177:3 186:9 240:16 331:20 331:21
appreciated 90:20 91:10 176:19,21 178:8
appreciates 177:13
apprised 321:22
approach 66:19 85:2 182:3,4,5 184:15 327:15
approaches 85:12
appropriate 156:19 157:15 171:17 203:13 231:18 308:3,7 309:7,13 310:9 312:7,8 334:6
appropriateness 155:16,22
approval 248:4 255:22
approve 265:1 309:6
approximately 19:4 29:6,9 155:7 294:16 332:8
April 26:19 29:4 30:6 32:15 55:14,21
ARCOS 61:1,6 61:9 261:11 317:13
area 21:3 29:20 44:8 90:9 158:18
areas 309:4
argued 221:24
ARNOLD 3:18
arrested 9:22 10:8 278:2
article 277:17 277:24 278:14 291:16 297:9 298:2,4 301:9
ascertain 149:12 156:18
ASFENDIS 2:19
asked 23:10 79:5 81:22 113:6 132:1 196:8 204:19 263:12,23 270:24
asking 14:7,10 14:13 32:17 50:14 80:23 130:15 167:10 196:5 201:21 216:23 218:8 227:2 285:7 319:13,14
aspects 62:21
assess 130:23 155:15,21
assessment 11:11 208:24 210:2,4 318:24 318:24 319:4,5 320:18 327:18
assessments 210:22 235:1 321:4
assistant 45:18 45:19 165:8 171:6 276:12

assisting 47:22
association 43:24 44:10,13 44:16 70:5 79:1 117:9,17 117:22 118:4 118:13,15 231:6
associations 43:6 44:3,7 227:4
assume 14:23 23:3 35:6 58:24 90:18 99:10 171:14
Assumes 281:17 314:8
assuming 284:5
assumption 40:19 169:9,16
assurance 38:21 59:17,21 230:12
assure 187:8
attached 10:18 40:2 250:23 289:22 304:24 307:17 308:2 334:12 336:11
attaching 76:23 106:15
Attachment 6:14
attempt 166:6
attend 44:4 127:16
attended 42:23 66:6 127:14 226:14,21,22
attendee 186:21 186:22,23 191:19
attendees 109:16 110:2 128:1,1 135:9
attending 127:7 128:5 135:17
attention 72:21 264:22 313:12 315:21,24
attest 172:9
attorney 305:3 334:16
audience 66:1,1 66:3,9
audit 30:16 86:13,15,17,19 142:20 154:15
audited 86:3,10 86:11 97:7,16
auditor 30:11
audits 30:16,18 30:19,20 48:13 48:18,21 49:4 49:6,17 62:20 86:6 98:5,9,10 98:13 224:20 234:14,18 322:1
August 287:14 306:6
automated 111:13,24 119:21 120:3,6 148:7 149:3 164:18 180:24 181:7 189:24 315:19
automatic 53:3
automation 126:15
available 149:24 150:3,18 154:5 155:12 199:3
Avenue 2:8
average 273:20
averaging 139:21
avoid 316:8
aware 68:15 69:21 91:12 92:2,4 93:10 98:4 103:16,19 131:17 132:18 133:11 144:11 144:15 161:23 162:4 172:15 172:20 173:3,4 173:9 243:19 294:20 295:5 295:13 313:24 314:11 316:5 325:14 326:15 328:14,24 329:10,22 330:22 331:15 331:18

B

B 5:12 6:2 7:2 8:2 9:2 10:2 11:2 58:23
back 36:22 57:14 59:22 81:5 88:8 92:5 119:13 120:20 136:7 137:15 172:13 179:11 183:24 190:7 211:1 220:3 257:6 266:17 267:10 274:11 296:14 310:4
background 31:12 36:7 42:10 202:10 203:11 212:1 216:21 217:9 217:13 231:7 231:11 245:15
Bar 44:15
base 155:8
based 46:9 47:5 75:15 111:9 132:16 136:3 140:6 144:20 145:16 146:8 148:4 149:8 161:24 162:21 167:7 178:19 179:1,23 213:11 222:18 224:1 237:15 238:11 239:23 243:4 262:13 282:13 285:7 285:16 288:15 309:21 310:8 312:6,14 313:8
basic 198:23 199:1 200:23 204:3
basically 37:7 47:22 53:18 67:23 156:24 211:22
basis 104:4,5 139:17 140:19 149:22 150:16 151:15 154:4 154:13,18 158:5 162:1 316:3 322:17 327:2,9 331:8
Bates 6:11 24:2 56:2 191:20
bears 64:19 65:7
beginning 1:17 62:9 73:9 88:15 96:5,6 98:24 111:1 122:7 156:6 193:15 266:18 297:15
begun 156:5
behalf 172:22 201:18
behavior 167:17
believe 37:1 38:12,18 48:12 49:3 81:12,23 89:3 108:10 113:24 138:11 146:7 251:24 286:20 311:18 315:14
believed 124:11
belonged 297:17
BENSON 3:3
Bergman 296:17 296:18 297:9 299:18
best 48:1 72:14 114:14 120:16 142:8,14 221:2 228:9 231:10 231:20 232:3 233:3,7 326:18
better 57:9 134:23 135:4 135:18
beyond 159:21 160:2,4 235:12
billion 67:19
bio 5:18 32:6
birth 194:4 197:3
bits 199:19,20
black 291:9
blind 207:20
block 253:2 300:9 301:12
blocks 253:20
board 198:11 199:3 205:11 213:19,22 257:12 258:18 260:4,11,16,23 264:6 267:2 304:8,19 305:1 305:3 314:5,23 315:1,8
boards 199:3 302:21
Bob 112:19 113:2 115:13 115:14,16,22 116:10 121:19 125:4
boil 122:11

bottom 39:21 56:3 104:13 247:16 307:15
Boulevard 2:3
box 84:13 183:20 258:1
brainer 194:15
branches 45:23 57:22
break 15:8,11 15:12 54:23 87:7,24 88:6 137:7,12 145:13 219:18 220:1 296:7,12 308:10
Brian 46:19 48:16 234:2
Brian's 49:2
Bridgeside 2:3
briefly 62:7
bring 22:10 121:17 264:21 313:12
broad 71:11 298:23
brought 20:17 20:19 23:1 60:19 315:20
BS 31:12
bullet 70:20 71:1 242:24 294:15
bunch 118:8
BURLING 3:2
business 22:4,8 28:7,11 33:20 33:20 34:4,10 34:18,24 35:15 67:18 168:11 221:21 231:9 231:13 323:1
businesses 235:18
buttons 321:20
buy 218:6,14,21
buying 221:7
Buzzeo 24:9 58:18 62:1,8,9 62:10,16,17 63:1 65:4,14 66:4 73:10 75:11 77:10,16 78:1 80:1,3,22 81:6,13 83:22 84:4 85:13 86:4,11,14,17 86:17 87:19 97:19,24 98:11 103:3,7,8,10 103:11,15,16 103:21,23,24 113:3 115:15 116:4 117:9,16 119:9,10 138:6 138:15,21 139:1,8,11 142:12 143:5 145:14,20 146:17 149:10 150:5,13,22 154:21 162:19 163:14 182:6 185:19 190:16 224:16 225:4 236:11,24 237:17 242:12 267:23
Buzzeo's 118:5 118:7 121:3 149:9 181:15

C

C 2:8
C-II 304:10
C.F.R 6:18
California 3:20 9:21 10:7 277:10,15 278:1
call 19:1,3 34:7 34:16 82:11 103:23,24 211:10 256:8 256:11 261:9 261:16,20 318:7
called 30:8 39:12 104:24 105:6 109:13 127:20,21 176:4 208:11 209:14,16 258:7 274:7 279:7 281:14
calling 235:13 259:10,14
calls 223:20 258:16
Canadian 58:23
cancel 265:2,3 265:12 301:6
canceled 157:14 157:20
capture 149:17
captured 123:3
Cardinal 2:16
careful 162:9,16 163:5
carefully 208:10 231:18 309:5 334:4
carisoprodol 315:12
Carolina 2:4
case 20:6,7,12 73:17 108:20 210:11 250:7 271:1 280:2 283:20 284:1
cases 1:7 236:15
Cash 235:20
cash-only 235:18
categories 156:19
categorization 288:19
categorize 153:14
categorized 288:15
category 321:1
cause 304:9
caused 287:19
CE 27:14,20
Cegedim 65:3 118:2 185:18 190:16 191:16 192:18 194:8 202:16 211:5 239:21 241:2 247:16 248:16 249:8 290:3
Cegedim's 190:22
censures 260:18
center 229:4
centers 37:11,24 38:5,8
Centre 3:14
certain 75:14,22 91:11,13 197:19 244:23 263:12 322:12
certainly 302:15 302:18 313:11
certificate 33:20 34:3 35:3 333:2
certification 27:21 37:9,10 37:19,20,23 38:2 222:11 224:15,18 333:18
Certified 1:18 1:18 333:13,14
certify 27:11 30:17 333:5 336:5
certifying 333:22
cetera 142:1 254:5,21 255:3 256:3 282:4
CFR 9:10
chain 227:19 228:24 229:5 229:15,19 230:3 250:2
chains 104:15
chairman 296:20
challenge 222:22,22
challenges 6:9 70:10
chance 25:1
change 37:5,16 98:18,21,22 99:1,2,4 101:4 178:23 182:8 217:1 250:11 250:13 335:4
changed 36:23 37:4,7,22 59:10 60:5 89:4 149:16 160:22,24 233:11
changes 99:23 100:4 103:16 103:20 180:5 182:15 225:7 275:2 334:11 336:10
changing 187:5
channels 176:17
characterizati... 84:5
charge 142:11 259:15 306:4 306:16
charged 291:17 297:12
charges 10:14 304:9 305:2
chart 40:3,9 41:7,9 45:6

57:21 77:21 78:23 81:1,5 81:20 82:10,18 82:21 83:16,19 84:5 86:2 183:1 184:11 185:11 261:5,6 265:24
check 181:17 203:11 245:15 302:21 326:4
checked 323:2
chemical 16:2
chemicals 16:3,5 16:11,14,16
Choice 234:21
chose 83:16,18 97:2 103:8
chronologically 93:16
circumstances 207:21 311:8
circumvent 316:8
citation 69:18
City 297:11
claims 60:19
Clancy 57:23 60:1
clarification 117:15 161:8
clarifications 168:4
clarified 167:17
clarify 167:5 171:15 208:2
clarifying 166:7 166:16 167:4 167:11,12 195:6
class 159:23 160:16 161:9 253:18
classes 34:1
classify 164:16
CLE 43:9 44:24
cleaner 174:6
clear 28:19 132:5 143:21 161:21 162:2 162:14 163:4 191:3 256:4 264:14,21
cleared 157:12 157:18 161:24 247:2 253:4 284:20 312:5
clearing 246:24 247:6 282:12 282:13 284:24
clearly 68:12,22 120:7 166:8 247:18
client 202:2,22 233:10 237:18 290:20
client's 212:4
clients 67:15 193:14 196:22 196:24
clients' 202:13
clinic 132:16 234:22 235:7 287:18,22 288:4
clinical 323:20
clinics 9:8 67:13 234:11 235:10 235:17 236:4
closed 327:17,21
closer 99:14
Code 6:17,20
coded 288:7
codes 110:23 114:23 124:9 242:16,21
coding 288:10
collaboration 86:11
collaborative 86:4,24 100:11
colleagues 326:20
college 43:15,16
Columbia 33:19 34:4
combination 320:22
combined 67:5
come 57:14 136:10 221:5 261:16,21 264:14
comes 257:6 262:2
coming 85:6 182:1
comment 248:14 255:8 285:5 290:12 291:10 292:9 309:18 310:16
comments 187:4
commission 336:21
commonly 278:3
communication 35:20 166:21 187:12 283:24 285:1 330:12
communicatio... 87:17
companies 3:23 221:16,20 228:7
company 3:16 23:10,14 27:11 30:7 57:8 62:12,15 66:24 67:20 68:19 73:18 74:12 87:4,11,16 106:13 135:23 185:18 196:18 200:11 202:18 255:14 325:8
comparing 189:2
competitors 66:11 117:23
complaint 298:14
complete 185:12 300:4,16 303:17
completed 15:10 84:9 183:7,9 184:12 185:8 242:22 243:17
completely 108:5 209:7
completing 176:15
completion 84:15 183:19 333:8
compliance 5:20 6:15 8:20 29:11,19,23 31:8 39:12 40:10,12,14,16 47:4 49:13,24 50:6,10,15,18 60:10 66:19 67:24 72:14 89:15 106:12 113:1 116:18 121:24 125:11 142:13 164:20 169:19 170:5,9 170:13 226:7 226:18 227:5,9 232:11 235:4 243:23 244:4,7 294:11 306:23 314:19 316:17 330:10
complying 168:19 169:17 169:23 170:11
component 54:3
comprehensive 301:15
comprised 228:6
319:6
computer 11:11 107:14 120:4 120:11 181:7 182:9,11,12,13 182:16,20,21 182:22 189:14 189:23 242:16 315:18 321:14
computerized 143:9,24 324:15
concept 155:1 157:5,6 230:8
concepts 167:17 168:3 170:16 238:12
concern 129:12 135:18 136:1 218:3,9,17 221:12 222:17 225:11 262:17
concerned 219:8 263:13
concerning 42:18 219:1 261:12
concerns 135:10 135:23 221:8 235:8 327:22
concluded 332:7
conclusions 242:11 247:17
conduct 129:8 176:13 208:23 208:23 222:23 224:19 257:10 257:11
conducted 86:19 133:21 139:20 140:10 146:11 149:12 156:16 156:22 162:10 183:14 202:11 212:2 216:22 217:10,14

234:18 245:20 270:6
conducting 48:13 154:21 234:13 235:1 315:3
conducts 209:14
conduit 132:14
conference 6:11 66:2,18 118:3 118:6,7,17 121:3
conferences 42:23 43:5,24 44:4,17,21 66:4 226:15,21 226:22
confidential 1:9 109:14 110:11 122:4 234:1,9
CONFIDENT... 1:10
confirm 300:5
confusing 268:20
Congress 91:11
congressional 91:14
conjunction 77:9 78:1 80:21 83:21 84:3 85:13 103:15
connection 291:17
consider 173:15
consideration 158:24
considered 16:8 243:6 249:12
consisted 43:4
consistent 77:11 78:2 86:7 117:4 140:11 145:1,7 150:6 150:11,24 152:7 159:8 227:10 228:11 290:2,22 295:8 308:15 319:9
consistently 316:2
constant 104:2
constantly 244:16
constitute 168:13
constituted 252:6
consult 200:12 270:24
consultant 62:10 97:20,24 103:2 147:1 199:6 248:16
consultants 116:1,4,6 224:19
consulted 77:15
consulting 62:13 63:2,6 65:14 119:10
Cont'd 3:1 4:1 6:2 7:2 8:2 9:2 10:2 11:2 137:20
contact 87:17 257:19,23,23 258:3
contacted 262:7
containing 155:13 156:17 232:15 315:11
context 78:20 135:5 208:3
contingent 213:21
continual 331:7
continue 59:18
continues 239:10
continuing 310:22
continuously 100:15
control 7:8 16:12 105:7 156:16 165:9 168:13 171:8 242:15 273:3 276:14 297:16 321:18 333:21
controlled 6:10 8:15 16:8,11 21:3,15 29:15 29:20 31:3 36:19 38:10,17 41:3 42:12,18 42:24 47:16 48:2,3,8,23 49:7,10,13 51:14 66:2 67:9 68:1,5,9 70:15 89:13,23 90:1,6 91:12 91:14,23 94:9 106:14,17,21 118:2 130:10 134:9 140:3 142:21 143:10 144:1 155:12 158:7 159:9 165:17 167:22 168:12 169:13 170:1 171:10 172:16 173:7 174:16,19 176:7,16 187:9 191:24 192:3 192:15 194:5 196:1 197:5 200:22 202:14 202:22 203:14 204:23 212:5 213:17 215:23 218:7,15,21 221:3,19 227:17 228:23 229:8 230:13 232:5 235:9 236:5 238:11 238:22 239:11 243:15 245:12 251:6 270:16 271:18 273:19 273:21 276:3,7 277:12,14 289:19 297:12 297:21 298:20 300:10 301:7 301:12,21 302:24 304:12 306:13 307:24 309:1 314:4 315:7,13 316:11,24 320:21,23 321:1,12 322:19 324:24 325:19 326:6 329:3
controlling 187:14
controls 40:17 207:16
conversationa... 64:6
convey 235:6
convicted 203:24 215:12 218:24
conviction 212:20 214:11 218:11,12
convictions 202:12,20,23 203:21 212:3 212:16 214:20 215:21 299:10
COO 296:20
cooperative 320:19
coordinate 62:4
coordination 244:19
copied 104:11 286:23
copies 197:22 198:6 250:22
copy 17:13,15 106:15 174:7
copying 106:9 234:6
copyright 278:4
corner 56:3
Corp 15:24 16:1 16:2 26:5
corporate 5:21 37:8,21 38:1 39:13 40:11 106:16
Corporation 3:6 57:5
correct 19:11 23:2,7 24:7,15 24:19 25:2 26:6,9,11,14 26:22,23 30:9 30:12 31:13 32:1 33:4,11 33:12,15,18 35:5 36:8,13 36:19,20 37:14 37:15 42:3,4,8 42:13,14 44:2 44:2,5 46:24 49:15 50:17,22 51:2,3,10,21 52:1,2,16,22 52:23 53:4 54:12 55:14,15 55:18,19,22 56:22,24 57:1 57:9 59:2,16 60:12,15 61:1 61:2 63:3 65:5 65:16,19,20 67:16,21 68:2 68:3,9,10 69:3 69:4,10 70:5

74:24 75:23 80:12,13 83:17 85:13,14,20,21 87:4,5,13,21 87:22 89:15,16 90:7,14,17,21 90:22 91:7 92:19 106:7,8 109:21 111:15 112:11 113:4 113:19,22 116:4 119:2,10 119:12 121:9 121:14 122:8 122:20 123:1 123:18 124:15 125:13,21,22 126:2,3,6 135:3 138:8,10 138:14,19 141:22 142:2,3 142:15,23 143:6,7,18 144:12 145:3 145:20,24 146:9 147:9,10 148:1 154:16 155:3,4 157:2 157:3,6 163:10 166:12 167:1,2 167:24 168:6,7 168:17,18,22 168:23 169:3 170:19,20 173:24 183:1 183:10 184:1 185:5,6,10,19 186:1 189:11 189:20 208:12 208:18 209:17 211:11,17,22 219:2 223:21 226:11,19 233:19 238:6,7 238:8,13 239:1 239:7,8,12,15 240:3,4 241:7 241:8 245:7 246:19 252:4 252:10,11,14 253:1,9 255:4 255:19,20,22 256:5,8,16,22 257:2,21 258:21 259:6 259:18,23 260:14,15,18 260:19,24 261:1 264:11 264:12,15,16 264:22,23 265:4,9 268:1 268:7,23 269:5 271:20,24 272:1 274:5 275:11,12 280:23 282:6,9 282:17 283:3 283:15 284:6 284:10,22 285:10,19 286:12 287:6 291:1 292:16 293:1,11 294:4 294:5 298:20 299:11 300:18 300:22 301:9 303:1,5,14,16 307:10,14 313:14 314:15 314:16,21 317:9,10,20 318:22 319:21 320:9 322:10 336:7

corrections 334:5,7 336:10

correctly 97:23

correspondence 241:18 242:2 243:13

Cosby 297:17,20 298:5,8 300:1

cost 225:18

costly 135:21

costs 225:8

counsel 14:10,20 15:23 17:20 18:9 19:6,9 20:17,19 22:9 22:19 23:1 26:4,19 242:19

countries 67:18

country 172:1 172:18 173:9

counts 298:9,11 299:5,6

county 60:19,21

course 14:8 22:4 22:8 288:22 315:5

courses 34:1 35:10,12,17,18 35:19,24 36:3

court 1:1 13:16 14:17 334:20

courtesy 329:2

cover 64:20 303:24

covering 220:17

COVINGTON 3:2

Craig 46:19 109:17 126:4,8 234:5 250:3,21 255:11 278:12 280:15 283:7 283:21 285:21 307:8,9,16 309:24 313:15

create 111:24

created 239:24 272:3,7,18

creating 125:12

credits 34:2 35:10 43:9

criminal 203:11 203:21 215:21 298:14

criteria 175:9 177:10 180:16 180:16,23 181:3 245:23

criterion 179:2

critical 227:18 228:23

cross-reference 323:19

crosscheck 323:4

CSA 168:20 269:4

cumulative 139:24

curious 45:5

current 6:9 15:21,22 25:14 73:24 140:6 154:14 158:23 253:21 321:21 322:14 323:16 324:14 327:15 327:23

currently 92:15 92:17 135:13 149:23 150:17 154:4 155:14 165:20 171:12 326:7

curriculum 25:14 43:15

Custodial 6:6

customer 9:15 70:12,16,23 71:4,7,17 72:3 96:10,16,17 129:9,20 130:3 130:9,16 131:20 132:10 132:16 133:18 155:8 157:5,8 159:13,15,18 159:24 160:18 161:22 162:3 162:10,15 163:2,5 168:6 168:16,21 170:17 173:13 178:19 179:23 184:19,22 189:2 190:4,11 194:6 198:3,15 198:24 199:1 200:20 202:19 203:9,14 212:12,18 214:14,18 218:19,20 223:10,16,21 225:12 230:21 231:8,12 232:2 232:5 235:12 236:9 237:22 238:7,9,10,12 238:21,22 239:4,10 247:22 248:19 253:7,8,19 257:19,24 258:3 259:10 261:14 265:3 270:17 271:14 271:17 273:13 273:17 274:11 283:15 284:21 290:3,7,19,24 292:15,24 293:9,23 295:21 299:14 300:18 302:1 307:18 308:4,8 308:13,16,22 310:7 311:3,6 329:2

customer' 232:13 294:13 294:16

customer's 155:16,22 231:9,13 243:5

243:14 262:4
customers 67:11 131:4 132:2 169:4,22 187:10 191:18 192:8 198:8 201:3 211:20 211:21 212:12 217:16,18 222:5,18 223:3 224:11,15,21 224:22,23 229:9 234:14 242:5 244:5 245:22 246:6 246:18 273:5 273:24 274:16 275:6 277:19 293:11 294:17 294:22 295:19 316:8
customers' 77:5
cutting 237:18

D

D 5:2
D.C 3:4
daily 104:4 140:19 222:1 222:20 274:1
Dallas 2:9
DAN 1:5
dangerous 322:20 327:18
Darby 297:22 300:1
data 61:1 140:5 140:6 149:22 150:2,6,10,16 151:15 154:3 261:11 328:10
database 323:3
databases 107:13
date 1:17 13:5 39:21 40:4 55:20 57:3 64:24 71:22 73:13,15 74:22 75:4 81:1,16 81:24 82:11,14 83:5,6 99:19 108:10 111:7 121:4,7,8,21 122:5,6 126:1 126:15 133:23 138:13 191:16 191:21 228:2 242:18 246:10 277:5 316:1 320:11 334:9 336:16
dated 76:21 138:21 166:18 185:23 220:16 239:22 240:8 240:13 250:4 271:11 314:13 324:16 333:15
dates 26:8,22 42:6 74:15 84:14 194:4 197:3 320:14
David 41:12,13 41:16 42:6 45:15 60:14 108:14 297:10
day 3:8 14:8 18:3,4 148:19 149:6 273:22 336:20
day-to-day 94:20
days 334:16
DEA 6:9,13,15 7:19,21 8:6 9:18 43:2 46:11,15,17 47:3 48:18,18 48:21 49:5,5 49:24 50:5,10 57:24 58:4,8 58:15,19,21 59:1 60:10 62:16,18,22 66:19 67:24 68:16,16 69:12 71:14 72:14 80:5,11 89:15 90:9 98:1 104:6 105:11 106:12 109:4 113:1 116:19 122:1 125:11 127:1,8 128:16 130:22 131:6 131:17 132:2,3 132:5,11,18 133:16,20 134:2,8,19 135:11 142:7 142:13 157:16 159:3 164:11 164:21 166:19 167:16 170:19 170:21 172:7 174:18 175:13 176:11 177:6 184:6 187:20 188:15 198:10 198:11 199:4 204:4,5,7,21 205:3,6,8,20 207:19,23 213:15,21 214:12 215:3,8 221:2,6 226:7 226:18 227:5 235:3,5,13 241:19 242:3 243:5,7 249:10 252:7 255:2 257:12 258:19 259:13,13 260:11 261:7,7 261:9 262:7,13 262:16,18 263:1,5,8,12 263:20 264:5 265:15,23 266:21,24 267:1,13 269:24 270:10 271:16 276:5 282:4 297:16 298:8 299:23 300:7,14 301:3 302:21 310:2,5 311:13 312:11 319:5,15,19 321:2,20 324:13 325:4,8 330:10
DEA's 129:1,6 166:6 187:4,11 294:11 311:17
deal 89:13 104:12,12 247:19
dealing 21:1 38:7
dear 69:14
death 277:15
deaths 9:22 10:8 277:11,18 278:2 291:18
debate 180:2
debating 180:9
decade 218:23
December 69:12 69:19 80:4 174:2,8 175:14 175:19 187:12 240:13,21 241:19 242:19 243:9 246:14 297:15 306:5 318:23 320:12 322:15 330:7
decide 102:22 301:21
decided 110:12 114:10 122:14 136:6,7
decipher 64:23
decision 52:19 52:21 75:21 103:11 109:3 253:2 311:22 312:8,9,14 326:2
decisionmaker 326:22
decisionmakers 328:1 330:15
decisionmakers' 325:17
decisions 107:23 327:6,8
dedicated 140:18
deemed 71:9,15 157:20 209:21 252:23 265:10 267:16 270:6 270:12,13 334:19
deeper 235:11
deeply 225:24
Defendant 2:16 2:22 3:5,11,16
Defendants 3:22
defer 74:1,7
define 190:20
defined 92:7 248:1,10,21
defines 143:1
defining 166:8
definitely 120:15 257:23
definition 91:5 177:6 269:4 270:4
definitions 95:21 96:1
degree 33:3,16
degrees 294:18 295:7
deliver 229:8
delivered 241:19

Demerol 297:19
demonstrate 164:20
Dendrite 65:3 75:11 118:2 185:18 192:18 193:23 211:5 239:22 246:15
dental 27:15 28:13 67:11 297:22
dentist 28:14
dentists 155:10
deny 180:12
departed 322:9
department 45:12 50:20,24 51:10,17 52:1 52:22 53:4 59:7 61:4 94:21,22 95:8 96:24 98:7 100:10 101:23 103:7 108:4 110:18 114:12 116:15 122:16 136:8,19 148:18 205:12 237:17 244:20 245:7 247:5,22 247:23,24 256:15 259:4,7 261:17,22,24 287:5,7 298:7 302:20 305:22 305:23 313:13 317:2,4,9 319:2,17 325:15,18 327:9 330:13
department's 264:8
departments 244:22 245:8 248:9,19
departure 59:8 330:1
dependence 93:1
dependent 298:11,13 299:8
depending 205:13 210:20
depends 312:1
deponent 13:12 336:2
deposed 15:6
deposing 334:16
deposition 1:15 5:16 12:2 13:7 17:16,17,19,23 18:1 19:9 25:10 332:4,7 333:6,8,9 334:3,13,17,19
depositions 107:13
deps@golkow... 1:22
deputy 15:23 26:4 165:8 276:12
Des 304:11 306:9,11,14
describe 120:8
describes 176:8 232:14
DESCRIPTI... 5:15 6:5 7:5 8:5 9:5 10:5 11:5
design 68:14,17 68:24 83:7
designated 73:17 74:11
designed 77:9 78:1 80:21 81:7,14 83:21 84:3 85:12 103:15 111:23 114:2 227:13
designing 68:7 69:5 90:3
detail 286:8
detailed 197:3 272:3,8
detected 94:17 175:13
detecting 173:16
detection 51:18 51:18 317:18
determine 71:7 139:22 142:5 142:12 154:24 176:15 192:14 195:24 202:11 212:2
determined 297:20
detrimental 91:24
develop 27:10 62:1 134:3
developed 243:24
developing 247:20
development 77:5 82:1 83:7 242:14
deviate 329:13 330:2
deviates 188:23
deviating 91:2 143:3 175:6 177:8
deviation 143:12 144:3,23 145:19 147:14 147:21 148:5 148:13 189:24 239:6 267:12 267:19 268:21 268:24 269:3 269:16,23
deviations 146:19 147:4,5 148:24 149:17 178:9 189:9
device 27:19
devices 27:24 28:3,5,9,13,16 28:20
diagram 251:15 251:17 327:24
Diaz 291:16 292:10
DiBELLO 1:15 5:5,18 6:7 13:13,20 15:18 26:3 128:2 138:2 333:8 336:16
DiBello-1 5:16
DiBello-10 7:10
DiBello-11 7:13
DiBello-12 7:17
DiBello-13 7:19
DiBello-14 7:21
DiBello-15 8:6
DiBello-16 8:9
DiBello-17 8:12
DiBello-18 8:14
DiBello-19 8:17
DiBello-2 5:18
DiBello-20 8:20
DiBello-21 9:6
DiBello-22 9:10
DiBello-23 9:12
DiBello-24 9:15
DiBello-25 9:18
DiBello-26 9:20
DiBello-27 10:6
DiBello-28 10:10
DiBello-29 10:13
DiBello-3 5:20
DiBello-30 10:17
DiBello-31 10:20
DiBello-32 11:6
DiBello-33 11:9
DiBello-4 6:6
DiBello-5 6:9
DiBello-6 6:13
DiBello-7 6:17
DiBello-8 6:20
DiBello-9 7:6
didactic 44:22
different 45:23 57:7,7 59:5 62:21 82:12 118:9 170:7 173:13 177:15 179:1 180:16 208:4 209:5 221:21 222:4,4 230:7,7 232:19 266:6
differently 144:11 153:22 178:4
difficult 206:16 301:18
Dilaudid 297:19
diligence 48:13 49:4,6,12 77:5 96:9 129:9 133:18,21 135:19 160:7 160:12,15 161:6 184:20 192:4,7,11 193:5,15 195:21 196:14 204:7,23 205:21 208:12 208:18,20 209:3,6,15,16 209:23 210:10 211:6,10 212:13,21 221:15 225:12 229:6,12 230:11,16,22 232:13 234:14 236:24 237:6

238:13,24 243:2,11 244:5 245:23 257:17 260:13 262:5 264:10 274:15 279:5,10 283:14 284:18 290:24 292:2 294:16,19,23 295:6,8,20,21 299:2,9 300:16 300:17 302:18 302:21 303:15 308:16 310:10 330:17

direct 60:3 72:21 174:23 257:19 333:21

Direction 12:5

directives 27:19

directly 45:14 59:14,14 88:13 126:6,7,8 139:10,14 241:17 255:11

director 17:1 22:12 26:18,24 37:1,6 38:21 38:24 42:15 88:18,19,24 89:4,12 90:24 91:8,19 92:10 92:13,21 93:4 93:12 94:11 95:11,18 96:18 96:23 97:6,22 98:6,15,21 99:7 100:19 129:19 130:1 138:10,12 165:12 173:22 175:17 185:15 185:21 201:21 203:10 204:17 218:4 219:6 229:20 271:23 275:23 288:2 290:17 292:13 294:3 314:2,18 315:21 320:3 321:5 322:10 323:24 328:16 328:23 330:8 330:20 331:9

disagree 151:8 156:7,11 197:14 199:11

disagreed 197:18

disclaimers 249:7

disclose 68:8 90:4

discovered 90:10,13 158:19 174:22 176:12 298:8 315:3

discovery 270:1 316:4

discuss 131:13 221:2

discussed 20:11 20:14 66:5 99:21 112:20 112:23 116:12 116:16 121:23 154:21 222:9

discussing 178:16

discussion 80:7 101:10

discussions 101:13

disjunctive 175:9 177:11 177:14 178:10

disjunctively 147:5

dispense 230:14 301:21

dispensed 305:5

dispensers 131:3

dispensers' 131:4

dispensing 131:14 168:12 169:24 234:21 298:12 299:6,7

distinct 51:1 52:14

distinction 23:22 50:13 208:6

distribute 16:17

distribution 7:15 8:21 10:15 27:16,21 37:11,23 38:4 38:8 40:23 44:11,12 47:17 91:21 127:23 221:3 228:7

distributor 16:3 47:11 67:3 68:6 128:17 132:15 133:4,5 168:9,15 173:14 207:16 207:17 229:18 231:7,11,20 232:1,4 321:1

distributor's 6:10 90:2 131:13 232:17

distributors 66:9,15,18 72:2 80:6 117:24 118:9 118:11 129:7 130:23 131:2,7 131:19 132:11 133:3,8,17 134:3,8,19 165:18 166:1,8 168:5 171:11 172:15 174:17 225:9 229:5,11 230:13 231:6 276:4

distributors' 227:11

DISTRICT 1:1 1:2

dive 235:12

diversion 165:9 167:16,18,23 171:7 173:17 207:17 227:17 228:22 229:13 229:24 236:20 276:13 317:18

diverted 176:17

division 1:3 158:17 176:11

Dmigliori@m... 2:5

doctor 9:22 10:8 10:14 159:23 161:8 169:21 169:23 170:3,5 203:13,22 204:21 205:20 209:19 212:16 213:16 214:10 215:11,20,23 218:5,9,23 236:15 260:24 262:8,17,17,21 263:14 264:7 277:10,14 278:1,16 280:6 280:11 282:15 282:16 283:3 284:2,9 285:4 289:24 291:16 292:1 297:11 297:11 300:6 301:1,2 302:6 302:23 307:19 309:8,21 310:20 311:11 312:3,4,16

doctor's 169:12 169:19 170:6,7 203:21 209:1 213:4 300:8 301:7,11 302:10 303:9

doctor-related 277:18

doctors 155:9 169:3 170:13 217:14 236:19

doctors' 205:5 208:15,16 293:15

document 17:8 24:1,5 25:17 39:4,11 40:22 54:24 64:13 76:11 89:17 93:18 94:8 109:7,12 113:19 118:22 122:11 125:21 127:3,20,21 137:1,4,22 143:17,22 145:3,23 147:2 160:10 164:22 167:8 170:24 174:10 175:22 176:3,19 177:6 177:19,21 179:7,8,9,12 182:2 186:6 187:14,24 190:19 191:11 191:22 196:6 200:21 202:2 211:3,15,22 216:19 217:4 220:5 225:19 230:19 233:21 234:7 238:3 239:16 240:7 244:10 246:14 246:19,20 248:13 249:3,4

249:20 254:11 255:13 268:4 268:10,11 269:12 271:6 271:13 272:10 273:18 274:11 275:15 277:20 282:18,19 286:4 293:16 297:4 303:12 303:18 307:2 313:19 318:4 318:11,16
documentation 232:15 292:20 326:23 329:5
documented 123:6 245:24
documenting 293:6
documents 12:8 18:22 19:20 20:16,18,21,24 21:1,12,17,18 21:20,21 22:1 22:2,5,6,10,17 22:18,23,24 23:5,9,9,14,15 44:18 78:6,9 93:16 158:15 197:20 267:18
doing 49:3,4 63:12 98:13 195:12 234:12 235:11 238:23 258:17 259:5 269:20 326:18 334:8
DOJ 7:19,21 8:6 9:18
dollar 321:13
domestic 36:7,9 36:11 37:16,20
Don 14:5 23:24 32:11 59:11 60:4 161:3 266:2,5
DONALD 2:3
Donna 104:18 104:19,21 106:10
doubt 122:22 134:11
Downing 4:6
Dr 139:20 198:16 213:12 292:10 300:1
draft 7:13 8:10 127:21 176:5
drop 30:4
Droz 11:7
drug 7:8 9:22 10:8 43:6 44:14,16 92:7 92:14,14,23 93:9,11 105:8 106:10,21 155:13,17,23 156:17 157:2 165:19 171:12 172:1,6,10 173:4 212:17 214:11 215:12 218:5,9,24 278:2 298:10 298:13 299:7 323:20
drug-coated 28:16
drug-dependent 301:22 302:9
drug-related 214:20 277:11
drugs 10:15 92:5,6,22 93:6 172:17 173:7 221:4 271:18 273:3,19 291:22 322:21
due 37:5 48:13 49:4,5,12 77:5 96:9 129:9 133:18,21 135:18 160:7 160:12,15 161:6 184:20 192:4,7 193:15 195:21 196:14 204:7,23 205:21 208:11 208:18,20 209:3,5,14,16 209:23 210:10 211:6,10 212:12,21 221:14 225:12 229:6,12 230:10,16,21 232:13 234:13 236:23 237:6 238:12,23 243:2,11 244:5 245:23 257:17 260:13 262:5 264:9 274:15 279:5,10 283:14 284:18 290:23 292:2 294:16,18,23 295:6,7,20,21 299:2,8 300:16 300:17 302:17 302:20 303:15 308:16 310:10 315:15 330:17
duly 13:21 333:5
dynamic 163:21 244:15

E

E 2:19 5:2,12 6:2 7:2 8:2 9:2 10:2 11:2 137:18,18 335:1
e-mail 6:13 7:6 8:17 9:12,20 10:6,13,17,20 104:11 220:12 220:17 222:15 250:2,3,19 273:12 278:5 279:13 281:11 281:12 285:17 303:23,24 307:6,16 309:22 310:9 312:7,19 313:4 313:9
e-mails 23:4 104:12
earlier 49:24 66:5 80:7 81:1 142:23 226:20 260:3 269:14 293:24 314:15
early 88:16 99:15 267:18
earth 211:2
easily 164:19
EASTERN 1:3
educational 31:11 35:23
Edwards 107:15 107:17 262:6 271:3
effect 91:24 130:4
effective 56:24 87:2 130:4 207:16 317:17
effectively 59:4
effectiveness 321:23
effort 86:4,24 100:12 320:19
efforts 135:14
either 18:8 20:4 20:10 23:21 35:11,22 45:4 78:9 87:18 112:9 153:12 206:13 257:9 281:12
electrical 31:13
electronic 53:1,7 135:14
electronically 149:2 197:17
emphasis 187:6
employed 178:17
employee 128:17 131:13
employees 67:17 248:2
employer 16:23
employment 26:22
enacted 90:16
endeavor 135:21
Endo 3:22,22
ends 56:1
energy 247:19
enforcement 324:13 325:5
engaged 136:18
engagement 62:1 103:21
engineer/lead 30:11
engineering 31:13
enhance 227:20 229:1 330:12
enhanced 62:2 133:18,22 180:3,11 244:16 329:24
enhancement 82:4,8,12 244:18 330:19
enhancements 62:5 82:24 180:6 219:15 244:24 245:3
enjoying 214:4
ensure 40:16 94:16 106:17 154:13 162:16

232:10
entered 140:13 262:12 305:15
entire 26:24 41:18 43:3,11 86:18 244:11
entirety 228:5
entitled 278:1 294:8
entry 140:9
errata 334:6,9 334:12,15 336:12
error 315:15
errors 321:15,19
escalated 51:24 52:18 218:18 264:11 292:13 299:16
Esq 2:3,7,8,14 2:19 3:3,9,13 3:18,19 4:6
essential 317:16
essentially 59:6
establish 95:21 96:1
established 196:12,15 242:3
et 142:1 254:5 254:20 255:2 256:3 282:4
Europe 27:22
European 30:1 38:2 67:6
evaluate 131:3 132:3 203:16
evaluating 169:19
evenings 35:7,9
event 52:11 132:15,19 134:21 311:13 312:11
eventually 278:7
evidence 281:17 314:9
evolutionary 100:5,8 123:4 244:15
exact 38:23 48:5 54:15 108:10 138:13
exactly 41:24 54:14 60:2 208:22 269:13
examination 13:24 28:12 137:20
examine 208:10
examined 13:22
example 24:10 102:22 227:6 260:17 326:1
examples 168:4 226:19 227:3 252:9
exceeds 162:11
Excellence 33:21
exception 291:6
exceptions 293:14
excerpt 68:4 70:1
excessive 144:21 145:17 154:24 161:21 162:2 162:15 163:4 167:20 300:8 300:15 301:4
exchange 220:12 222:12 303:23 307:7
excuse 28:7 45:16
Excused 332:6
executive 7:17 33:23 34:7,8 34:15 138:23 139:19
executives 34:16
exempted 292:2
exhibit 17:9,13 17:15 25:18,22 39:5,8,10 55:1 55:4,12 57:20 64:14,17 76:12 76:16 78:21,21 80:17 81:2 84:10,11 85:1 89:18,22 93:19 93:22 104:10 109:8,11,12 119:14 120:17 120:20,23,24 121:1,17,18 127:2,4 136:7 137:23 138:3 138:20 164:23 165:2 171:1,4 174:11 175:23 176:2 179:11 180:14 186:4,7 191:12,15 206:17 207:7 216:20 220:6,9 225:20,23 227:8 233:22 234:1 239:17 239:20 240:4 249:21,24 271:7,10 275:16 277:21 282:22,23 286:3,5 293:17 293:20 297:5,8 303:19,22 307:3,6 313:20 313:23 318:17 318:20
exhibits 84:20
existed 52:14 96:22 97:6 129:21 130:9 322:9
existence 181:5
existing 96:17 98:19 140:2 162:9 165:24
expand 134:8,19 187:16 188:5,6 188:6,7,11 189:4
expanded 29:10 37:8 189:10 245:12
expansion 37:24
expect 135:11 170:12 292:15 292:19
expectations 242:3 243:17
expected 131:7 133:20 134:2,8 134:19
expecting 133:16
expects 131:1
expensive 135:11 136:16 225:12
experience 35:23 36:6 55:17 88:13 135:15 261:8
expertise 135:12
expires 336:21
explain 212:19 311:7
explaining 166:20
explanation 159:16 161:16 162:17 165:24 190:6,13
export 5:20 39:12 40:10,12 40:14,17,19
exposed 327:16
express 327:22
expressed 135:9
expressly 206:6
extend 227:11
extensive 155:14
extent 22:11 73:21 97:5 160:6,11,21 164:19 248:1 264:5
external 7:14 23:8 127:23
extremely 301:17
eye 207:20

F

F 137:18
f/k/a 3:23
face 125:20 166:24 238:3 312:18 313:4
faced 172:1
faces 10:14 165:20 171:13
facilitate 62:4
facilitated 138:6 196:17 221:1
facilities 235:2
facility 236:16 304:5
fact 45:3 72:12 83:7 93:10 116:3,9 118:17 136:6,8 205:20 207:18 210:7 214:2 215:12 218:22 249:15 322:23
factor 170:2 312:24
facts 281:17 314:8
fail 334:18
failed 306:17 329:12 330:1
fair 43:12,18 51:19 66:20 74:23 79:19 81:4 84:22

96:20 138:7 219:12
fairness 326:17
faith 316:10
familiar 34:21 60:23 69:13 109:1 245:16 273:4,9,14 275:7 296:3 319:10
family 287:18 287:22 288:3
far 131:12 256:7 278:22
FARRELL 2:13
fashion 149:3
fast 273:12
favors 291:22
fax 1:22 273:12
fbenson@cov.... 3:5
FDA 43:1 48:19 58:15
February 1:12 13:5 170:21 171:5,24 173:23 206:4 206:24 207:1,4 207:4,10,23 220:11,16,18 250:4 251:10 257:18 267:14 269:22 333:15
federal 6:17 301:20 317:19
feel 229:23
feeling 327:15
felons 204:1
felt 70:10
field 157:16 158:17 272:18
Fifth 159:11
Figueroa 3:19
figure 124:13,19
figuring 110:20 114:21 124:7 124:13 125:8 136:9
file 6:6 55:6 57:12 105:12 161:18 209:19 262:4,5,20 280:15 285:24 289:24 290:8 290:14,19 291:1 292:4,16 302:8 303:15 303:17 304:9 307:17 308:2 310:16
filed 316:2
files 7:8 24:11 105:8 106:10 106:21 165:7 209:15,16 210:10 294:19 294:24 295:21
filing 159:1
fill 88:11 273:17 284:22 308:13 309:10
filled 130:24 190:4,8
filling 242:6
final 182:23 280:1 283:19 285:20,24
finalized 85:3,17 184:16 185:4
finally 58:22
find 206:9 210:24 249:10 270:23
finding 144:19 144:19 145:14 149:20 150:14 153:12 154:1 155:5 156:8,11 157:9 159:11 235:22 236:1 279:22 305:4 323:23 324:21
findings 91:11 91:13,14,17 105:16 144:10 164:10 181:15 187:15 237:16 322:13,13 323:7 327:4
finds 158:15
fine 53:11,12 64:4 173:1 197:24 254:9
finished 184:7
firm 14:6 43:9
first 13:21 17:22 18:5,12 26:21 36:14 40:8 51:16 53:18,24 62:23 70:20 78:21 81:6 85:19 88:17 89:13 93:21,24 94:24 95:18 98:18,21 99:1 99:2,4,19,19 112:21 116:12 122:13 144:18 144:19 145:14 157:16 159:23 160:14,16 161:6,8,12 186:20 193:24 212:7 227:7 231:1,4 232:20 248:12 250:19 252:10 253:15 253:18 254:24 255:3 272:10 278:12 281:22 281:24 282:5 288:12,20 294:10,14 296:2 307:16 319:11
fit 169:21
five 45:23 105:9 105:13 106:11 106:21 107:11
five-year 106:24 107:4,7,8
flag 111:19 112:1 113:18 115:7 124:20 126:16 136:12 237:11,14
flagging 141:3
flags 71:16 140:20 141:8 147:3
Floor 2:20 3:14 3:19
flowchart 54:18 59:3 253:21 255:15,22 256:9 258:5,15 258:21,22 259:4 264:5 265:8 267:8 270:8 280:9,17 281:6,8 282:1 327:24
focus 49:22 214:5
folks 109:16 113:15 114:9 115:3 116:8 122:10,24 327:7
follow 6:15 53:9 132:6 147:16
follow-up 162:20 211:15 286:2 310:3
followed 279:13
following 257:9 261:3 297:15
follows 13:22
food 43:6 44:14 44:16
foregoing 333:18 336:6
Forest 297:11
form 53:6 66:13 72:6 74:3 81:10 82:20 85:23 94:5 102:6,21 103:3 111:11 112:4 112:13 113:21 114:4 116:24 117:13 118:21 119:24 123:21 124:24 125:15 126:19 127:10 129:8,14,23 130:13 131:9 131:22 132:23 133:18 134:13 135:1 136:14 136:22 141:15 144:14 145:5 146:2 147:19 151:7,23 152:21 153:3 158:10 160:9 161:11 162:24 164:14 166:3 169:7 172:3,22 177:18 180:18 183:12 187:23 189:13 192:23 193:19 194:10 195:18 197:8 197:12 199:9 200:7,14 201:5 202:5 203:4 205:2,24 212:24 216:2 217:3,21 219:4 223:12,23 225:15 237:2 237:20 238:15 239:14 243:23 244:7 246:8 247:9 252:16 253:23 259:20 261:19 262:10 262:24 263:18 263:23 265:6

265:18 268:3,9 269:7 273:7 281:5,16 283:17 285:12 289:2 290:5,10 291:3 292:6,18 293:3,4 295:3 295:11,15,24 297:17,18 298:22 300:20 302:4 303:7 305:8 306:19 308:6,14,19 309:16 310:13 311:1,5,15 312:22 313:6 314:8 317:22 321:7 322:3 323:12 324:9 324:18 325:11 327:11 328:5 328:19 329:7 329:16 330:4 330:24 331:13 331:16 336:10

formal 43:13,14 43:16 149:21 150:15 151:11 151:13 152:3,6 152:13,14 153:1 154:2,8 154:10 155:14 155:21 156:16 255:13,17,22 258:12

formalized 151:17,21 157:1

former 62:16

formerly 185:19

formulated 322:17

forth 67:23

forward 163:19 188:17 217:12 219:10

forwarded 175:20 248:5 277:16 278:9 297:9 306:2 313:15

forwarding 278:5

found 155:6 161:16 235:2 235:17 304:8 311:11 323:16 328:9

foundation 67:24 161:11 192:23 193:8 193:19 194:10 200:14 201:5 202:5 216:2 217:7 246:8 247:9 252:16 261:19 262:10 262:24 263:23 289:3 308:19

four 35:11 99:12 179:1 279:17 280:8 281:24 283:9 284:9 285:18 287:13 287:22 288:21

fourth 157:9

frame 48:5 101:3,16 102:19 220:10

FREDERICK 3:3

frequencies 190:2

frequency 91:4 143:5,12 144:3 144:22 145:18 146:13,20 147:5,16,17,21 148:4,12 149:14,17 175:8 177:10 178:9 181:18 182:15 189:1,8 238:5,20 239:7 267:12,20

FRITZ 2:13

front 45:6 50:23 51:9 117:19 119:14 120:18 120:21 138:20 211:3 216:20 236:19 282:21 285:8,17

frowned 309:3

full 15:9,16 214:6 240:1 329:4

fully 164:18

function 29:11 60:3 140:14 198:21 201:14 209:20,21 216:4 224:4 255:6 258:20 258:20 259:16 259:17 260:21 270:21 285:6 290:13 307:1 316:15 317:2

functions 48:18 317:14

fundamental 189:5 209:10

furnished 190:5 190:12

further 1:10 132:20 159:24 160:19 163:11 227:11 232:15 241:18 266:4 289:7 297:19 327:20

future 106:13 162:14 163:4 270:16 307:23

FYI 278:15

G

Gantt 184:11

gap 32:4,11

gather 22:17 232:20

general 15:23 26:4 43:7,7 46:8 47:8 69:23 71:11 92:1 187:4 243:16 291:5 298:24 305:3

generalization 66:20

generally 28:15 164:5,7 275:2 300:21

genesis 83:10

gentleman 20:1

getting 75:15 176:24

GIBBONS 2:18

GIV 46:8 47:6 47:11,15,16 112:22 116:14

give 14:20 78:19 210:8 214:2 268:18

given 20:5 73:23 104:10 159:1 207:14 210:16 298:8 333:6 336:8

giving 65:21 76:17 80:18 102:18

glad 14:14

gloves 28:12

go 15:13 41:5 47:1 53:14 54:20,22 56:1 56:16 70:9 73:1 88:19 93:15 104:13 112:18 128:10 130:22 142:19 144:18 178:2 179:11 181:13 199:18 204:20 225:24 230:18 242:10 255:1,1 255:1,2 256:4 261:23 267:10 270:18,19 278:5,21 284:19 289:7 301:5 318:1

goal 83:1 221:5 230:16

goes 140:17 173:12 175:3 232:18 257:7 327:14

going 14:6,9,23 17:12 26:16 54:20,21 64:4 76:15 80:17 81:4 86:22 88:4 92:5 93:15 120:19 121:16 135:21 136:6 139:7 148:15,17 163:19 182:19 188:17 208:9 210:24 214:2,4 216:10 219:10 219:18 220:17 225:24 230:18 253:16 266:17 268:18 282:3

Golkow 1:21 13:4

good 14:3,4 63:13 203:1,6 203:9 217:19 217:23 278:15 298:6,16 299:13 316:10

Google 252:7 255:1 282:3

Gotcha 28:23

gotten 165:14

328:2
govern 242:15
government 30:19 67:14
governs 90:2
Gray 1:17 333:12
great 56:17 247:19
greater 230:11
group 44:16 45:21 46:7,10 46:14,17 50:11 50:16 65:15 95:14 96:4 100:24 101:3 101:19,19 104:22 105:24 116:10 123:10 123:19 124:3 124:11,17 125:6 136:4 198:9 205:4 236:4 245:1,1 286:16 291:12 312:13 326:14 326:16
growing 172:18 173:8 227:16 228:21
guarantee 249:9
guess 78:11 97:13 216:7,8 216:9,11
guessing 206:19
guidance 70:22 71:3,14,21 72:1,12 132:20 165:23 226:3,5 227:8 231:5 233:12,14 241:16 325:2 325:21
guidances 227:1 227:1 232:21
guidelines 8:21 8:22 166:9 227:10 228:11 228:14,20 232:11
gut 327:15

H

H 5:12 6:2 7:2 8:2 9:2 10:2 11:2
half 19:4
halfway 63:14
hand 120:23
handing 14:9
handle 95:15 192:3,15 196:1
handled 51:8 305:22
handouts 44:24
hang 56:4 78:13 78:14 195:16 195:17 206:9 289:1
Hannahoe 110:6
happen 64:5 285:18
happened 32:17 89:7 138:13 183:20 252:3,9 263:7 312:2 315:17
happening 257:20 304:15
happens 64:7
happy 15:8
hard 25:7 197:21 198:5
HARRIS 3:9
hazardous 43:1
HAZMAT 46:12 49:22
HBC 3:16
HDA 126:24 133:14
HDMA 7:13 8:18 44:4 71:24 72:3,13 72:17 127:1,8 127:12 130:8 130:15 220:15 221:1 226:3,4 226:10,13,14 226:18,23 228:6 231:5 233:4 236:11 236:24
HDMA-DEA 127:22
he'll 63:18 309:11
head 286:11,14 319:19
headed 319:16
health 2:17 3:22 44:11,12 67:13 91:24 172:18 173:8 205:13
healthcare 8:21 67:3
hear 14:14
heard 272:22
hearing 10:18 204:8
held 1:16 13:8 251:23
help 62:3,17 87:15 105:17 229:7 232:10
helping 102:22 227:19 229:1
Henry 2:11 4:3 4:6 5:16,17,19 5:20 6:6,8,12 6:17,19 7:6,9 7:12,16,18,21 8:6,8,11,12,14 8:17,20 9:6,9 9:12,15,17,20 10:6,10,12,16 10:20 11:6,8 13:3 17:1,2,6 20:22,23 21:12 21:12 23:5,17 23:19,20 24:2 24:10 26:17 28:18,19 32:21 32:24 33:3,8 33:10 35:4 36:15,22 37:11 37:20 38:4 39:11,15 40:9 40:24 41:7 47:12 51:14 53:22 60:18,24 61:23 62:11 63:2,6 66:18 67:2 68:16 69:3,6 72:2,12 73:18 74:11 77:4,8,23 80:19 81:8 83:20 86:5,12 87:11,18,19 90:12,19 91:9 91:20 92:21 93:5,13 96:17 100:1 106:20 107:3,5 109:13 111:2,8 112:2 116:22 117:9 118:18 119:19 121:20 126:15 128:2 132:19 135:16,22 136:6,17 138:22 142:12 143:8,23 144:20 145:15 145:22 150:8 154:2,23 155:7 155:20 165:6 165:11 169:2 169:11,22 170:2,22 172:19,23 173:23 174:7 175:18 176:3 178:8 190:23 192:1 201:1,15 201:18 203:10 204:18 206:6 208:17 209:12 212:10,18,19 212:22 214:14 214:16 215:19 218:7 222:1,16 222:19 223:1,4 223:9 224:8,13 226:9,12 228:14 229:21 229:23 233:4 234:14 245:20 246:3,15 247:18 268:22 271:12 275:19 277:13 294:21 296:21 297:23 299:4 300:1 301:8 302:1 303:13 304:10 305:1,4 306:21 308:17 309:1 310:19 311:23 314:3 315:6 316:2,5,10,16 317:1 325:16 328:24 330:11 331:10,12
Hi 307:16
HIDA 44:12
high 92:8 287:17 320:24 324:14 325:5,8
highlight 143:10 144:1 146:19
highlighted 129:6 144:22 145:18 149:13 157:10
HIGHLY 1:9
hire 27:3
hired 27:5 147:1 248:17
historical 76:18

history 53:15 77:3 80:19 105:9,12 243:15 261:13 261:14 269:24 288:2
hold 38:20 251:21 265:22
holder 192:12 193:6 195:22
Holdings 3:24
HON 1:5
hope 292:14
hopeful 15:14
Hopefully 14:11
hot 321:20
hour 15:12 19:4
hours 22:24 236:17
HSI 156:21 158:22 221:21
HSI's 143:14 144:5
HSI-MDL-00... 9:16
HSI-MDL-00... 9:14
HSI-MDL-00... 10:22
HSI-MDL-00... 8:22
HSI-MDL-00... 9:19
HSI-MDL-00... 10:11
HSI-MDL-00... 7:8
HSI-MDL-00... 7:22
HSI-MDL-00... 10:9
HSI-MDL-00... 5:22
HSI-MDL-00... 8:16
HSI-MDL-00... 9:23
HSI-MDL-00... 8:10
HSI-MDL-00... 8:19
HSI-MDL-00... 7:11
HSI-MDL-00... 8:13
HSI-MDL-00... 7:20
HSI-MDL-00... 11:7
HSI-MDL-00... 8:7
HSI-MDL-00... 7:17
HSI-MDL-00... 9:11
HSI-MDL-00... 6:14
HSI-MDL-00... 10:19
HSI-MDL-00... 11:12
HSI-MDL-00... 10:15
HSI-MDL-00... 7:15
HSI-MDL-00... 9:8
HSI-MDL-00... 6:7
human 225:13 324:6
hydrocodone 93:9,11
hypothetical 214:22 216:17 219:4 268:19 281:6,16 283:17 292:18

I

i.e 235:3
idea 217:19,23
Ideas 299:19
identification 17:9 25:18 39:5 55:1 64:14 76:12 89:18 93:19 109:8 127:4 137:23 164:23 171:1 174:11 175:23 186:7 191:12 220:6 225:20 233:22 239:17 249:21 271:7 275:16 277:21 286:5 293:17 297:5 303:19 307:3 313:20 318:17 320:21
identified 120:4 237:11 327:19
identify 143:11 144:2 181:9 301:18
identifying 150:5
II 51:16 92:6,14 92:22 93:6 306:8
III 93:9,11
IKEDA 3:18
illegal 91:20 311:19
illegally 187:10 291:20
image 322:24
immediate 41:15 75:13,22 76:1 79:14,17 79:20 190:24
immediately 54:6 110:22 114:22 124:8 124:12,18 125:9 158:3 159:4 191:7 267:14 268:1 269:23 270:7
impact 203:12
imperative 334:14
implement 27:10 62:3,4 97:14 201:2,10 244:23
implementation 73:10 82:2 83:8 84:8 85:7 183:19 240:1,2 241:6,7,11,12 249:8 315:18
implementatio... 183:3
implemented 27:20 58:17 76:5,7 77:14 79:18 81:7 84:13,21 85:19 97:7,13 102:15 111:23 119:19 182:23 183:22 184:19 185:1,8 193:13 201:8 201:13,16,23 202:19 210:22 211:4 212:11 217:1 219:10 219:14 233:8 249:16,18 250:11 251:1 251:12 258:13 259:1 275:5 321:24
implementing 38:3 102:4,9 192:7 227:12 233:2 274:4
import 16:17
important 23:22 170:2 212:21 230:4,6
importation 91:21
importer 16:3
impossible 222:2 301:18
impracticality 222:17
improper 10:14 91:22 219:4 281:5,16 283:17 292:18
improve 227:13
improved 244:16
improvement 244:18 330:19
inappropriate 238:22 325:3
include 29:10 41:2 67:11 91:1 109:16 175:5 179:21 187:7 194:1,22 194:23 208:15 210:1,3 315:13
included 28:6,10 30:16,18 43:21 128:14 133:15 243:24 286:10 315:11
includes 67:8 146:12 157:17 192:10 306:5
including 30:20 36:18 49:7,9 98:3 124:4 135:10 143:2 197:1 205:5 224:23,24 242:14 258:9 259:12 292:24
inclusive 134:10 177:11
incomplete 316:6
inconsistency 153:15,19

164:10
inconsistent 83:23 84:2 145:22 146:6 158:6,13 164:16 294:19
increase 188:8 274:9,13,18
increased 274:23
increasing 275:1
independent 30:20 147:1 148:10 176:13 182:7
independently 146:21 175:12 232:1,4
INDEX 12:2
Indianapolis 297:24 304:4
indicated 263:2
indicates 68:12 68:22
indication 167:23 168:1 236:20
Indirectly 109:22
individual 10:10 164:7 169:4 189:3 248:2 294:8 324:23
individuals 46:16,18
industrial 16:5
industry 8:20 44:11,12 142:8 203:17 221:8 227:9 228:9 232:11
industry-wide 231:10
industrywide 221:5 223:1,5 223:6
inform 105:6 158:17 174:17 176:10 276:5
information 74:21 105:13 110:16 111:3 114:20 116:14 119:20 124:6 126:14 132:14 133:8 134:23 135:4 136:18 159:24 160:19 173:21 175:17 191:20 194:1,2 194:3,18,19 195:2,4,9,13 197:3 198:16 198:23 199:1 199:18,19 200:21 202:3 231:8,12,17,19 232:19 251:10 260:4 272:3,8 279:15,21 283:23 300:3 302:8 316:12
informations 122:16
informative 215:22
informed 146:18
informing 90:8
ingredient 178:21
ingredients 16:4 16:16 180:1 321:14
inherent 321:15
inherited 98:20
initial 27:22 51:5 187:15
initially 53:24
initiated 82:5 260:23
initiative 128:17
initiatives 227:13
injectables 46:8 47:8
injection 306:8 306:11,15
inquire 215:20
inquiries 173:14 211:7 236:10
inquiry 168:21 192:5,7,11 193:6 195:21 196:14 202:20 211:11 212:13 212:22 214:18 218:19 236:13 236:23 237:6 237:12 238:24 245:11,17 263:21 299:19 303:5,13
inspect 132:6,10
inspections 131:20
instances 325:21
Institute 31:15 43:7 44:14
institutions 67:15
instruct 308:12
INSTRUCTI... 334:1
instruments 28:12
insufficient 188:2 204:19 205:19
intake 193:15
integral 317:17
integrity 227:14
intelligible 14:11
intend 230:14
intends 273:2
intent 15:13 316:7
interact 62:9 317:11
interacted 139:10,16
interacting 139:13
interaction 101:10 104:3 302:11 309:20 312:15
interactions 87:10,18 115:17
interface 103:10
internal 23:5 86:6,13 111:3 315:4,5 318:24 322:1 326:22 327:6 330:9
international 27:12 30:22 37:14,19 40:20 40:23
internet 253:1 253:16,17,24 254:7,17
interoffice 9:6 11:9 234:2,10
interpose 14:21
interpret 151:10 167:14 189:23
interpretation 163:2 166:17 167:6,7 187:5 254:8
interrelations... 248:8
intervention 324:6
interview 193:24 194:20 195:12 196:24 200:19 257:11 259:5,10
interviewed 192:12 195:22
interviewing 198:4
interviews 257:1
inventory 155:12 156:21
invested 135:13 247:18
investigate 176:9 191:2 232:2,4 242:4 242:6
investigated 71:17 157:11
investigates 209:13
investigating 205:22 235:16 264:7
investigation 146:11 202:10 212:1 217:10 246:5 248:6 257:16 291:19 297:14,20 299:24 300:2
investigations 216:21 217:14 245:21 246:17 260:23
investigations/... 243:3
involved 51:23 53:19 54:1 61:24 62:24 95:12 109:6 111:2 136:9 186:15 246:24 299:23
involvement 247:7 325:9 331:6
involves 304:1
involving 8:15 191:24
Iowa 304:8,24 305:4
ISO 27:12,13

30:21,22 31:8 37:10,12,24
issue 36:17 104:6 105:19 105:21 200:12 228:15 315:2 316:5
issued 191:16,17 228:1
issues 8:14 36:18 38:9 42:17 191:23 200:23 211:16 221:11 235:7 302:23 328:15 330:18
issuing 298:10
item 84:12
iteration 65:4

J

Jackson 299:24
Janine 4:6
January 104:17 106:6 176:20 176:22 178:14 179:16 183:24 185:22 187:17 189:7 190:7,23 191:7,17,21 192:6,21 196:21 200:9 202:17 217:11 277:13 278:6 278:16,18 287:15,15 289:17,18,21 304:13 307:15
Jaysari 110:7
JD 107:15,17 262:6 271:3
JDE 10:21
Jeff 76:22 318:20 319:6 320:2
Jim 86:2 220:21 286:9,10 287:12 289:8
job 15:21,21,22 16:23 22:11 36:23 38:21 55:12,13
Joe 80:11 165:7 204:5,9 206:5 213:12,14 275:20
John 2:7 198:16
joined 128:24
joining 62:11,14 62:15
JONES 2:8 3:8 321:6 322:2 323:11 324:8 324:17 325:10 327:10 328:4 328:18 329:6 329:15 330:3 330:23 331:13 331:16,24
Joseph 171:5 174:9 276:11
journalism 34:19,22
jpmcdonald@... 2:10
judgment 248:2
July 41:10 76:21 116:21 185:4 289:21
jumps 228:18
June 30:6 39:23 184:20 185:2 275:9,20,23
justification 253:5,8 279:3 279:4,7,19 280:10,23 282:16 283:2,6 283:11 284:8 284:21 285:10 287:4,8 307:21 309:11,14 310:10 326:4 326:10,13
justified 288:4
justify 310:21

K

K 4:6 45:17
KAREN 3:19
karen.rigberg... 3:21
Kathleen 138:24 139:2 142:4 145:15
KAYE 3:18
keep 45:4 106:20
Ken 319:8,17,20 319:22,24 322:8
KEVIN 2:14
kicks 147:14
killers 291:21
kind 21:18 173:21 175:17 238:24 302:20 302:23 304:20 312:10
Kmulry@farr... 2:16
knew 115:20,22 299:18
know 9:15 21:20 21:21,23 22:7 22:16 27:17 28:13 29:24 43:8,14 48:6,9 49:5 54:17 60:2 62:19 70:16,22 71:3 71:8,17,20 72:3 77:4 79:16 86:22 96:16 97:14 100:15 101:8 102:24 103:23 104:2,4 105:12 106:24 107:2,3 107:5,10 125:24 128:20 129:20 130:2,7 130:8,15,16,20 132:10 148:14 153:4 157:5 166:18 168:6 168:16,21 169:17 170:17 172:10 173:13 179:6 180:7,22 184:18 190:19 190:20 193:12 193:13 195:8 198:21 199:15 201:15,20,22 202:1,17,19 203:9,22 206:17 208:24 209:19,19 212:10,14 216:12,14,15 217:5,11 219:11,13,15 220:24 223:15 223:16,17,18 223:19 224:8 224:12,17 225:1,4 228:10 229:16,18 230:21 232:12 232:20 233:7,9 236:9 238:7 239:4 240:17 244:6 247:11 249:14 251:4 258:1 263:7 266:1 270:21 270:23 271:13 271:17 272:9 272:12,13,15 272:21 283:18 287:24 289:4,6 289:14 293:22 294:12,15 295:20 299:4,9 302:1 305:14 307:18 308:4,8 308:16 309:19 309:19,21 313:7 324:1
knowing 70:12 131:19 157:7 238:12
knowledge 23:11 249:13
known 321:20
knows 172:24
Kowalski 10:22
Kyle 128:17,20 128:24 131:12 132:4,13 135:17

L

L 1:17 41:12,13 333:12
label 27:14 28:21
labeled 141:11
laboratories 30:5,8 32:3 36:6 55:18 67:12
lack 70:22 71:2 161:11 192:23 193:8,19 194:10 200:14 201:5 202:5 216:2 217:7 246:8 247:9 252:16 261:19 262:10,24 263:23 289:3 308:19
lacked 325:18
language 188:20
large 147:14 228:8 235:23 236:5 291:20 296:4

largest 67:3
late 163:23 318:13
laudable 327:16
launching 156:23
law 32:16 33:2 33:11,13,16 43:6,9 44:14 44:16 314:6 316:9,19
laws 168:20 169:18,20,23 170:11,12,13
lawyer 17:14 318:5
LAWYER'S 337:1
layer 52:13
lead 92:24 116:4
leadership 35:19 35:21
learn 226:18
learned 44:8
learning 277:9
leaves 327:16
leaving 21:11 307:7
led 328:1
left 17:7 20:22 32:2,14 46:22 50:1 87:3,11 87:15 275:10 275:10,13 277:3,6 293:22 294:21 314:14 320:7 326:10 327:5 328:15 328:22 329:21 330:8,20 331:8
legal 10:17 86:6 86:13 108:2,4 108:11,13,15 200:23 211:16 306:2,3
legally 230:14
legitimacy 235:6
legitimate 176:17 200:24 211:16 252:23
Len 41:16 42:6 45:15 59:11,12 59:15,21 60:13 297:10 299:17
lesser 222:7
let's 47:1 48:19 88:14 108:8 113:11 128:10 144:18 145:13 211:1 213:10 215:11 219:17
letter 7:19,21 8:6 9:18 11:6 56:21 69:12,19 70:3 71:20 80:5,8,10 159:14,18,22 160:16 161:7 161:18,19,20 161:24 162:2 162:13,22 163:3,10 165:3 165:6,11,16 167:1 170:23 171:9 172:9 174:3,15 184:6 184:24 187:13 190:5,12 204:5 206:4,10,24 207:2 208:1 213:13 241:22 241:23 253:6,7 253:18 256:4 256:13 258:4,9 275:20,21 276:3,8,10,17 278:23 279:1,3 279:6,8,19 280:10,23 282:17 283:2,6 283:11 284:18 284:21 287:4,8 309:11,14 310:3 314:13 315:1 317:7
letter's 161:15
letters 24:13 69:14,15 71:13 162:9 274:16 284:8 285:10 326:5,11,13
level 37:6 222:7 230:11 245:23 246:23 247:4 247:11 252:4 252:10 257:20 264:9,11,13 282:14 288:12 288:21 321:19 324:13 325:4,5
levels 209:5 222:4 317:19
license 170:6 195:2 198:11 198:12 203:23 204:3 205:12 213:5,5,20,22 214:12,22 215:8 260:9,14 298:17 300:7 300:14 301:2 305:6
licenses 194:2 194:12 195:6 197:2,15 205:5 205:10 215:14 260:2,6 301:20
licensure 142:1 252:8 255:2 256:3 282:4 284:19
lies 322:22
light 203:16
limit 146:15
limited 167:21 245:14 254:7 326:19
line 12:6,9,12,15 50:23 51:9 111:17 142:8 294:10 335:4 337:2
lines 236:16,19 237:9
linked 9:22 10:8 277:10 278:2
LinkedIn 25:23
Lisa 286:21,23
list 16:10 46:22 127:24 154:23 155:13 156:17
listed 41:11 186:20 235:7 258:19 287:18 287:21 298:6 314:18
listen 214:7 261:10
listing 288:3
lists 30:5 128:2
litigation 1:6,21 13:4,11 22:2,6 24:3 60:20
little 56:2 57:18 76:24 80:14 153:21 174:6 205:16 289:7 318:13
LLC 2:2
LLP 1:16 2:7 3:2,13,18
loaded 21:24
local 176:11
locate 22:20
location 131:15
Locke 1:16 2:7
Loiacono 46:19 48:15,16 49:1 234:4,5
long 15:13 19:1 19:15 29:5 38:20 312:5
long-term 331:3
longer 59:13 87:16 105:11 105:13 307:22 308:14 309:12
look 25:1 39:20 76:20 120:21 127:19 131:14 147:16 168:9 168:15 169:11 199:22 204:20 205:8,9 206:13 220:21 230:19 237:7 240:3 250:18 260:22 280:12,15,17 281:19 282:17 296:7 302:7
looked 24:24 57:11 117:5 320:20
looking 32:10 43:14 57:20 73:2 148:12 168:5 181:24 205:4 266:7 282:2 303:12
looks 56:15 289:9,19
loop 327:17,21
Lord 1:16 2:7
Los 3:20
lost 87:16
lot 62:19 86:21 101:9,9,10 103:1 107:12 225:13 235:17 254:3 272:16 289:10 327:5
lots 55:8 101:18 105:22 219:15
low 28:15 222:6 247:4
lower 246:23 250:19
lunch 137:7,12

M

Madeline 286:21
Maggie 110:4,5
mail 159:23 160:16 161:9 253:19
main 221:11
maintain 25:14 106:17 203:23 204:2 207:16 209:16 301:19
maintained 22:3 22:7 23:16,18 24:10 87:17 107:3,6 195:7 197:16 260:5
maintains 298:16
maintenance 204:6
majority 210:12
making 50:14 119:11 312:9
Malone 138:24 145:15
man 115:13
managed 94:20 97:7,10 100:8
management 9:7 27:11 35:20 37:9 38:3 234:11,22 247:2,7,12 248:4 252:13
manager 27:6,8 29:1 33:10 36:23 37:6 50:8 139:1 304:4 312:12
managing 232:16
manner 300:4
Manning 58:3 59:11
MANNIX 3:13
manual 5:21 39:13 40:11,15 140:9
manually 140:13 148:8 148:11
Manuals 44:24
manufacture 16:12,15 28:20 91:21
manufacturers 30:17 66:9 80:6 174:17 276:4
March 85:4
MARCUS 3:13
mark 27:14,20 46:20 47:20,24 48:6,12 54:22 109:19 126:5,9
marked 12:14 17:8 25:17 39:4 54:24 64:13 76:11 89:17 93:18 109:7 127:3 137:22 164:22 170:24 174:10 175:22 186:6 191:11 220:5 225:19 233:21 239:16 249:20 271:6 275:15 277:20 286:4 293:16 297:4 303:18 307:2 313:19 318:16
market 37:14 38:2 66:11 178:19 179:23 323:18
markets 67:6
marks 332:3
Marte 4:3 13:3
masks 28:11
masters 34:10 34:12
material 321:10
materiality 321:11
materially 328:12
materials 43:1 262:19
matter 13:9 99:11 128:13 305:12
Maurizio 59:20
MBA 33:23 34:5 34:8,13,15
McDONALD 2:7 23:23 24:7 24:15,19 32:9 32:19 53:5 56:4,8,12,15 63:9,17 66:12 72:5 74:2 76:8 78:13 81:9,21 82:15,19 85:22 94:4 102:5 111:10 112:3 112:12 113:20 114:3 116:23 117:12 118:20 119:2,23 123:20 124:23 125:14 126:18 127:9 129:13 129:22 130:12 131:8,21 132:22 134:12 134:24 136:13 136:21,24 137:3,6 141:14 144:13 145:4 146:1 147:18 151:2,6,22 152:20 153:2 158:9 160:8 161:2,10 162:23 164:13 166:2 169:6 172:2,21 176:23 177:17 177:23 180:17 183:11 186:2 187:22 189:12 192:19,22 193:7,18 194:9 195:16 196:4 196:11 197:7 197:11 199:8 200:6,13 201:4 201:17 202:4 203:3 205:1,23 206:8,14,21 207:1,5,7 212:23 214:7 214:21 215:2 216:1,8,12 217:2,6,20 219:3,17 223:11,22 225:14 237:1 237:19 238:14 239:13 240:5 240:10 246:7 247:8 252:15 253:22 254:3 254:10,15,18 259:19 261:18 262:9,23 263:17,22 265:5,17 266:1 266:5,14 268:2 268:8 269:6 272:14 273:6 280:24 281:4 281:15 282:7 283:16 284:11 285:11 289:1 290:4,9 291:2 292:5,17 293:2 295:2,10,14,23 298:21 300:19 302:3 303:2,6 305:7 306:18 308:5,18 309:15 310:12 310:24 311:4 311:14 312:21 313:5 314:7 317:21 318:6
McKesson 3:5
mean 20:24 36:11 44:23 49:11 62:19 79:17 86:21 120:2 148:7 156:10 180:8 208:20 213:8 254:13 268:13 289:13 306:21
Meaning 123:7
means 74:23 75:4 188:7 190:21 258:9 324:2 333:20
meant 254:17
measures 177:15
Med 245:11,17
medical 27:15 27:19,24 28:3 28:5,6,9,10 92:16,17 155:9 155:16,23 200:24 204:3 211:17 287:18 287:22 288:4 323:3 325:2,18 325:20 326:15 329:5 330:14
medically 326:8 326:12
medicine 203:24 213:6 227:15
meet 19:12,15 127:13 187:19
meeting 7:10,13 8:18 109:14 110:10,11,12 111:5,18 112:18,21,23 113:15 114:9

114:19 115:5 116:10,12,16 117:16 121:19 121:22 122:3 122:13 123:1,2 125:20 126:1 126:24 127:1,8 127:22 128:6 128:14,18,24 135:17 139:15 186:16 220:15 221:1,20 240:13
meetings 17:19 101:9,15,17,18 101:22 125:5 127:12,15,15 127:17 163:18 186:15 244:10
Melodie 304:2,3
Melville 17:3
member 44:13 44:15 71:24 72:17 226:10 226:12 227:19 228:24 230:3
members 133:14
membership 127:14 228:12
memo 113:13
memorandum 9:7 11:9 39:22 126:13 180:15 234:2,10,24 246:1
memory 73:24 74:1
Memphis 297:22
mention 49:23
mentioned 260:3 303:24
mere 204:6
merely 83:6 205:19
merged 31:16
message 207:22 208:1
met 19:16 235:2
metadata 64:23 177:1 240:18
methodology 140:2 159:20
methods 293:14
Michael 1:15 5:5,18 6:7 13:13,20 15:18 26:3 333:8 336:16
Michelle 1:17 333:12
microphones 88:3 137:9 219:22
mid 163:23
midlevel 155:10
Migliori 2:3 5:7 14:2,5 17:11 24:4,12,16,20 25:20 32:12,13 32:22 33:1 39:7 53:10 55:3 56:9,19 63:21 64:3,9 64:16 66:14 72:7 74:9 76:14 78:18 81:15 82:6,16 83:3 85:24 87:23 88:10 89:21 93:21,23 94:6 102:12 109:10 111:12 112:7,16 113:23 114:7 117:3,18 118:23 119:4 120:13 123:24 125:3,18 126:22 127:6 127:18 129:17 130:6,18 131:11,24 133:1 134:16 135:2 136:15 137:2,5 138:1 141:18 144:17 145:10 146:3 147:20 151:3 151:18 152:2 152:24 153:8 158:14 160:13 161:4,14 163:8 165:1 166:10 169:10 171:3 172:12 173:1,2 174:13 176:1 177:1,4,22 178:2,6 181:11 183:15 186:5,9 186:11 188:4 189:16 191:14 192:20 193:3 193:11,22 194:16 195:19 196:7,15,19 197:9,23 199:16 200:8 200:18 201:9 201:19 202:8 203:7 205:15 206:2,12,19,23 207:3,6,11 213:9 214:9,24 215:7 216:18 217:8,24 219:5 219:20 220:8 223:13,24 225:22 233:24 237:5,21 238:18 239:19 240:9,15,23 246:12 247:15 249:23 252:19 254:1,9,12,16 254:20,22 259:21 262:1 262:15 263:11 263:19 264:3 265:7,19,20 266:3,10,16 268:5,17 269:10 271:9 272:17 273:10 275:18 277:23 281:1,10,18 282:11 284:3 284:15 285:15 286:7 289:5 290:6,15 291:14 292:11 292:23 293:8 293:19 295:4 295:12,17 296:6,16 297:7 299:1 300:23 302:14 303:3 303:10,21 305:11 306:20 307:5 308:9,23 309:23 310:18 311:2,10,20 313:2,10,22 314:12 317:24 318:3,9,12,19 321:9 322:5 323:14 324:11 324:20 325:13 327:13 328:7 328:21 329:9 329:19 330:6 331:2,14,19
Mike 128:2 220:20,23 250:22 279:13
military 30:18
milliliters 306:7
Milton 60:4
mind 249:12
mine 45:4
mini 33:23 34:5 34:13
minimal 235:5
minimum 235:3 235:13
Minneapolis 3:10
Minnesota 3:10
minute 112:17
minutes 110:10 111:17 112:17 113:14 114:8 114:18 115:4 116:7 122:4,12 123:18 124:2 126:1 130:21 133:15 136:3 136:20
mirror 322:24
Mischaracteri... 118:21 160:9 180:18 187:23 217:3 268:3,9
mischaracteri... 50:21
miscommunic... 315:16
misinterpretat... 315:16
misrepresenta... 321:17
misstated 328:13
mistakenly 316:12
misuse 227:17 228:22 230:1
mm-hmm 108:23 237:14
mode 322:17
model 134:4 155:2 169:2 221:21 323:1
modifications 140:7
Moines 304:11 306:9,11,14
moment 265:16
Monday 278:18
monitor 100:16

monitoring 7:10 8:9 38:15 48:23 52:13 53:1,8,16,21 54:2 58:1,5,9 61:14,17,22 62:2,6 63:5 68:18 69:7 73:8,20 74:22 77:8,13,24 79:2 80:20 81:18 83:14,20 84:9 85:8 86:3 87:20 94:3,15 95:10 96:22 97:5,21 98:8 98:14,19 99:3 100:1 101:11 102:10 103:14 103:17 104:7 109:14 110:13 111:2,8 114:11 119:18 121:11 122:14 123:11 134:4 135:20 136:11 139:12 143:9,24 155:3 176:4 178:17 178:18,24 179:4,10,17,22 180:4,7,10,11 180:15 181:22 184:15 185:3 189:20 192:2 193:16 226:6 241:15 248:18 248:22 250:10 250:24 251:6 289:23 294:12 301:16 315:10 316:19 320:8 322:14,23 323:8,17 324:4 324:15 329:11 329:23 331:12

monitors 140:19

month 157:14 158:4,6 268:7 314:15

month's 159:7

monthly 158:5

months 139:24 288:23 320:4

morning 14:3,4 142:23 187:3

morphine 304:10 305:5 306:8,10,15

Motley 2:2 14:6

Mount 2:4

mouth 120:16 123:9

move 59:23 189:2 245:19

moved 54:5,8 59:12,22

moving 137:1,4

Mullins 286:9 286:10

MULRY 2:14

multi-special 288:8,10

multiple 245:2

N

N 5:2 137:18,18 137:18

name 13:2 14:5 15:17 20:2 28:21 64:19 65:7 75:12 93:17 107:15 107:20 115:13 234:3 272:19

narcotic 298:10 298:12 299:5,7

narcotics 297:18

nation 165:20 171:12

National 1:5 13:10

nationally 323:3

necessarily 179:9 235:6 252:12 269:9 298:17

necessary 14:21 221:10 334:4

need 15:8 71:16 115:6 188:10 221:16 238:19 281:11 291:21 302:7 303:16 310:15 318:7 329:5

needed 114:1 124:12,18,19 124:19 132:20 181:16,16 188:5 189:18 327:19

needs 78:14 111:18 113:16 187:16 267:23 267:24

negotiation 35:18

neutral 323:2

never 15:5 25:10 244:9 272:22 279:18 283:9 310:5 316:7

new 1:16,17 2:15,20,20 8:14 13:9,9 15:19 17:3 26:13 27:18 44:15 84:12 85:8 96:10 137:1,4 140:7 156:20,23 165:23 178:16 178:18,23 179:4,10,17,22 180:3,6,10,16 180:23 181:17 181:22,24 182:18 183:23 188:14 191:18 191:23 192:2,8 192:10,11,14 193:6,14,16 195:11,21,24 196:22,24 198:3,8 201:3 202:22 203:13 211:5,10,21 212:11,12,18 214:14,17,18 217:16,17 218:19 221:15 221:17 222:1 222:18,19 223:2,10 224:11,15,21 224:23,24 225:11 231:1 233:10 241:6 243:1,4,9,18 243:20 244:1,5 250:9,23 251:8 251:11 255:19 257:17 272:4,8 272:18 273:5,5 273:20,24 274:4,5,14,16 275:5 281:13 281:14 290:2,7 290:20 299:14 321:23 326:21

news 277:17 291:16 297:8 298:1,4 301:9

nice 55:8

nine 30:7

non-delegable 69:8

noncontrolled 168:14 169:14 236:6

nonmedical 172:16 173:6

Nope 61:13

normal 22:8 91:3 143:4,13 144:4 175:7 177:9 188:24 190:1 323:20

normalization 184:8

normalizing 322:18

normally 75:8 76:4 79:8

North 67:5

NORTHERN 1:2

Notary 1:19 333:14 336:23

notation 161:18

notations 326:23

note 262:20

noted 13:14 334:11 336:11

Notes 270:15 337:1

notice 1:16 5:16 10:18 17:16 277:8 304:12 304:21

noticed 261:10

notified 17:22 17:24 265:11 265:23 266:22 266:24 267:2 267:13

notifies 256:18

notify 133:2 256:14,17 315:1

November 64:24 71:23 75:5,21 228:3 232:22 232:24 240:8 240:20 287:14 304:1,7 314:14 314:23

number 17:13 24:2 25:22 33:24 39:9,10

55:13 56:2,2 64:18 78:21 119:14 120:17 120:23 121:17 121:18 127:2 135:9 136:7 156:8,11 171:4 179:12 216:20 220:10 221:14 222:19 227:8 239:21 240:4 243:6 245:14 250:1 273:20 274:10 296:4 313:24 318:20
numbers 194:5 197:4
numerous 163:17
nutritional 16:4
NW 3:3
NYU 31:13,16 31:18,20,21,22

O

O 137:18,18,18
oath 13:17
object 53:5 66:12 72:5 74:2 81:9 82:19 85:22 94:4 102:5 111:10 112:3 112:12 113:20 114:3 116:23 117:12 118:20 119:23 123:20 124:23 125:14 126:18 127:9 129:13,22 130:12 131:8 131:21 132:22 134:12,24 136:13,21 141:14 144:13 145:4 146:1 147:18 151:6 151:22 152:20 153:2 158:9 160:8 161:10 162:23 164:13 166:2 169:6 172:2,21 177:17 180:17 183:11 187:22 189:12 192:22 193:18 194:9 195:18 197:7 197:11 199:8 200:6,13 201:4 202:4 203:3 205:1,23 212:23 216:1 217:2,20 219:3 223:11,22 225:14 237:1 237:19 238:14 239:13 246:7 247:8 252:15 253:22 259:19 261:18 262:9 262:23 263:17 263:22 265:5 265:17 268:2,8 269:6 273:6 280:24 281:4 281:15 285:11 289:2,2 290:4 290:9 291:2 292:5,17 293:2 293:4 295:2,10 295:14,23 298:21 300:19 302:3 305:7 308:5,18 309:15 310:12 310:24 311:4 311:14 312:21 313:5 314:7 317:21 321:6 322:2 323:11 324:8,17 325:10 327:10 328:4,18 329:6 329:15 330:3 330:23 331:13 331:16
objection 14:21 81:21 82:15 151:2 192:19 193:8 217:6 283:16 303:2,6 306:18
objectionable 318:10
objections 282:8 284:12
obligation 68:15 71:4 90:11,12 90:21 168:16 174:21 239:3,5 301:24 316:9
obligations 60:24 70:15 71:18 72:4 89:14 96:16 129:21 130:9 130:11 132:9 166:1 173:15 176:7 187:20 308:17
observation 133:15 246:22 323:22 325:22
observations 149:9,9 323:7 327:4
observed 221:4
obtain 231:7,11
obvious 194:2 194:18 195:1 197:1 199:18 199:21,22 200:2,3
obviously 67:9 208:8 221:19
occasion 62:18
occasional 104:5
occasionally 63:19 263:6
occur 146:14
occurred 85:17 103:21
October 7:14 26:9 40:5 56:24 84:14,14 84:22 85:18 87:3 109:15 110:10,24 111:23 114:2 115:5,10 116:8 122:5 124:22 127:22 131:6 131:18 132:9 133:20 134:2 134:18 182:24 183:6,10,17,21 183:23 185:10 275:14 276:23 276:24 299:22 321:24 329:21
offenses 214:20
offered 71:21 87:14 132:13 133:2,7
office 26:12 37:21 157:16 158:17 165:9 171:7 236:17 243:16 273:20 276:13
office-based 67:4 155:8 222:5
offices 1:16
official 247:2
officials 221:7
Ohio 1:2 60:21 314:4,5,22 315:1,8 316:9 316:17,20
okay 14:24 15:7 15:20 16:18,22 18:5,12,19 19:19 22:22 24:4 25:8,9,24 26:2 27:3 31:17,23 32:19 32:22 33:2,7 34:6,14,23 35:2,14,22 39:3,14 40:8 41:5,17 42:1 43:23 44:18 45:22 46:2,21 47:10,19 48:9 49:23 50:8 54:11 55:7 56:17 57:16 58:22 60:16 61:11,20 62:7 63:8,16,24 64:24 65:1 66:22 70:1 71:5,22 72:19 72:23 74:14 75:5,19 76:8 76:19 77:2,6 79:12,15 80:16 81:16 82:7 83:4,11 84:7 84:17 85:11 87:1 88:3,7 89:6 94:24 97:18 98:2,4 99:16,22 100:7 100:13 101:20 104:9,14 105:4 113:11 114:18 115:24 116:7 117:19 118:5 119:8,13 120:18 123:8 124:1 125:19 126:23 130:21 138:15 139:9 141:19,23 143:20 145:11 148:20 156:6 157:9 159:11

160:3,23,23 163:13 166:22 168:2 171:19 171:21 177:5 179:15 184:23 186:22 187:2 188:19 198:14 201:20 204:16 207:9,10 209:8 209:11 210:19 211:1,18,23 213:24 214:5,8 215:13,13,18 223:19 224:8 225:6 227:7 228:13 229:3 230:7,9,23 231:3,14,21,22 231:24 240:15 241:4 244:8,13 245:4 246:13 248:15 249:6 250:20 252:20 254:15,23 255:24 256:1 256:20 264:4 265:13 266:15 266:20,20 276:18 279:12 282:24 283:7 284:4 285:16 287:1 291:13 296:22 300:24 302:15 304:6 306:4 307:12 308:1 310:1 311:21 317:15 319:3,20 320:10,15,17 322:12 324:3 326:17 329:20

okayed 252:24

older 106:11

omissions 321:17

omitted 316:12

on-site 131:20 256:21 258:16

on-the-job 43:20 43:21 227:4

onboarded 274:1

onboarding 96:10 191:18 196:22 233:10 239:9 299:13

once 66:8 87:15 251:20 252:2 265:21 267:22 279:19 283:21 303:9

ongoing 42:22 43:2 100:5 123:4 239:4 244:11 262:21 290:21

onsite 209:1 210:1,4,21 221:17 222:23 223:2 224:19 245:21 246:5 246:17

onus 261:3

open 242:14 250:8 251:1

opened 187:3 221:18 243:1,4 243:10

opening 186:23 187:1 231:1 237:10 243:18 243:20 244:1 273:1

opens 222:1,20

operate 68:14 68:18,24

operating 38:16 68:7 69:6 75:13 85:16 90:4 142:6 143:17,22 145:2,23 150:1 150:7,19,24 151:20 152:1,8 152:17,18 153:15 154:7 164:11 185:3 187:17,18 198:13 199:14 233:11 246:1,4 246:10,16 255:12,18 283:14 284:7 290:23 295:9 327:17 329:1

operation 170:8 290:23

operational 84:21

operationally 102:4

operations 221:13 304:4 314:19 315:4

opiate 1:6 13:10 47:17

opiates 16:20

opioid 16:21

opioid-related 277:18

opioids 51:16 93:5 230:1

opportunity 57:4,10 333:9

Opportunity/I... 10:11 294:8

opposed 208:5

ORD881 289:12

order 6:16 22:7 38:15 48:23 51:8 52:13 53:15,21 54:1 58:1,5,9 61:14 61:17,22 62:2 62:6 63:4 68:18 69:7 71:8 73:7,19 74:22 77:8,12 77:24 79:2 80:20 81:18 83:14,20 84:9 85:8 86:3 87:20 94:2,15 95:9,22 96:2 96:21 97:5,21 98:7,13,19 99:3,24 100:1 102:10,23 103:14,17 104:7,8 111:1 111:8 119:18 121:11 125:10 134:4 136:10 139:11 141:11 141:13 144:21 145:17 146:10 146:13,14 155:2 156:20 159:1,12,12,16 159:17,22 161:7,17,24 162:15 163:5 168:10 175:12 177:16 178:11 184:14 185:2 189:19 190:21 192:2 193:16 198:22 205:22 207:19 208:9 208:14,14 209:13,21 218:6 226:6 229:7,12,24 238:5,21,21 239:6 241:15 248:17,22 250:10,23 251:17 252:22 252:24 253:9 254:24 256:15 256:19 257:6 263:15 264:10 265:2,2,10,12 265:14,14 266:23 267:1,9 267:11,15,19 268:12,21,22 269:3,17,23 270:5 274:12 274:17 282:2,6 282:15 284:19 288:5,13 289:23 294:12 300:15 301:5,6 301:7,16 307:22 310:22 311:8,9 320:8 322:14,23 323:8,17 324:4 324:15 326:24 329:11,13,22 330:2 331:12

ordered 155:18 155:24 162:12

ordering 75:7 76:3 79:7 167:20 169:13 182:1 194:6 197:5 199:24 202:14,21 212:5 215:23 273:2,21 297:17 300:8

orders 51:4,13 51:19,23 53:2 68:9 90:5,9,13 91:1,2,2,4,6 94:17 101:11 111:20 112:1 113:18 115:8 124:21 126:17 128:12,14,24 129:2 130:23 131:3 132:17 133:10 134:5 134:20 135:6 136:12 139:21 140:20 141:3,8 141:20,21 143:2,2,3,4,11

143:11 144:2,2 144:21 145:17 147:4 148:4,19 149:6,13 157:10,17,19 157:23 158:3 158:19 159:2 160:7 161:21 162:3,21 173:17 174:18 174:21,24 175:5,5,6,8 176:11,14 177:7,8,9 178:19 179:23 181:2,10,17 182:1 187:7 188:15,17,18 188:22,23,24 190:4,8,20 191:2 208:4,7 226:5 236:5 239:11 242:6 247:1,1,6,13 262:21 265:22 270:3 274:10 274:14,18,23 275:1 276:6 278:21 281:9 281:23 283:9 284:9 285:9,19 287:12,13,19 287:23 288:22 289:9 303:9 307:24 328:2
ordinary 22:3
organizational 40:3,9 41:6,9 57:21
orient 320:16
oriented 323:10
original 242:13 254:6 334:15
outcome 305:18 305:20
outdated 45:3
outlining 166:9
outside 23:9,14 50:16,19 64:10 236:16
overburdened 324:5
override 287:22 288:4
oversight 54:7
overview 8:12 66:23 185:24 186:16
Oxford 3:14

P

P 2:7,14
P-E-N-D-S 51:5
P.C 2:13,18
p.m 88:9 137:10 137:16 219:23 220:4 296:10 296:15 332:5,8
page 5:15 6:5 7:5 8:5 9:5 10:5 11:5 12:6 12:9,12,15 25:23 39:20 40:6 41:6 56:1 56:6 72:21 77:1 117:19 120:21 127:19 138:23 167:15 173:12 186:19 207:10 227:7 230:20 240:12 242:11 250:19 251:15 265:24 266:9,11,11,12 266:14 267:7 267:10 278:1,6 278:12 307:16 335:4 337:2
pages 336:6
paid 200:12
pain 9:7 234:10 234:22 235:7,9 291:21
painkillers 278:3
Pal 110:7
papers 14:9
Par 3:23,24
paragraph 207:13 225:7
parameters 323:17
parse 188:12
part 31:18 34:19 54:3,6,9 57:17 58:18,21 61:11 90:1 91:5 108:3,11,13 109:2 110:5,7 128:1 131:19 150:12 167:11 178:5,22 191:24 194:13 196:22 211:10 226:17 229:15 229:19 243:4 244:4 260:20 279:10 288:16 299:13 310:6 317:16
part-time 33:13 35:7
participate 101:12
particular 18:2 35:15 71:7 132:21 148:6 149:1 186:17 208:14 209:18 222:15 228:15 235:12 236:4 241:14 260:5 261:14 263:9 271:1 276:17 280:6 283:20 284:1 291:6,7 302:6 312:15 326:21
particularly 21:2 51:15 228:17
parties 245:2,6
parts 97:9
party 24:8
pasfendis@gi... 2:21
pass 318:7
patient 308:1
patients 235:24 236:14 237:9 291:21 301:22 302:10,11
Patrick 110:6
Patrick's 110:8
pattern 91:3 146:20 147:6 147:17,22 148:4,12 175:7 177:9 178:10 182:7,15 188:24 214:3 238:5,20 239:7 267:12,20
patterns 143:4 143:13 144:4 144:23 145:19 146:13 148:23 148:24 159:13 178:20 179:24 181:18,23 189:3,9 190:1 322:19 323:21 329:14 330:2
PAUL 2:19 3:13
pause 63:18
paying 315:24
payment 291:23
PCDS 234:21 237:18
PDF 250:6 251:4
PDMA 77:10 84:4
Peacock 20:9,11 76:22 83:18 84:7 318:21 319:7 320:2
Peacock's 84:4 86:2
pedigree 135:14
pend 140:21 141:4,9,12 191:2 278:21 279:17 289:9
pended 51:23 96:2 141:20,22 157:17,22 159:22 162:21 247:1,1,6,13 251:17,21,22 252:2 254:23 256:15,19 264:10 265:14 265:22,23 267:11,15,22 268:13,22 274:14,18,22 274:24 280:8 280:20 281:22 281:24 282:6 282:15 283:9 284:9,18 285:9 285:19 287:13 287:13,23 288:5,13,22 303:9
pending 159:16 242:6 274:10
pends 51:5,5 146:11 159:12
Pennsylvania 2:19 3:14 298:7
people 59:4 60:11 92:1 109:24 148:17 149:4 299:8
perceived 233:15
percent 155:7 210:7 294:17

294:18,22 295:6,19
percentage 168:11 169:12 210:9 235:23 236:5
perform 133:17 211:6 221:17 229:6,12
performed 96:9 98:6 326:24
performing 204:22 238:23
period 26:15 29:17 31:1,5 34:2 35:13 48:12 52:3 53:24 54:16 93:8 102:2 108:11 140:23 163:23 225:4 229:22 234:19 289:10,20 314:1
periodic 149:22 150:16 151:15 154:4,13,18
permitted 308:24
person 18:8,20 19:12 50:9,12 52:9 58:16 73:17 74:11 139:6,7 186:20 207:18 298:13 298:18 304:19
personal 57:12 194:3
personally 74:20 232:22
personnel 55:6 326:8,12
persons 298:11
perspective 6:10 209:24 210:1 291:15
pertaining 200:22
Peter 49:21 50:3
ph 1:22
pharma 26:5 300:10
pharmaceutical 3:23,24 16:4 218:15
pharmaceutic... 3:23 301:12
pharmacies 169:5 221:22 236:19
pharmacist 143:15 144:6 149:23 150:17 154:5
pharmacists 260:18
pharmacy 132:16 168:19 168:24 169:17 198:12 205:11 213:20 257:13 258:18 260:11 260:16,24 264:6 267:2 302:22 304:8 304:20 305:4 314:5,23 315:2 315:8
pharmacy's 168:11 170:8 199:4 260:4 305:1
phase 232:13
phases 184:3
phone 18:8,19 18:21 19:1,3 195:12,15 196:9,23 197:21 198:17 198:18 199:13 211:9 223:20 257:11 258:16 259:5,9
physical 92:24 131:15
physician 67:12
Physician's 234:20
physicians 326:5
pick 121:7
picked 82:10 121:4 122:6 196:23
picking 181:16 182:14 189:8
pipe 76:10
Pittsburgh 3:14
place 22:14 40:16 73:20 94:8,16,19 95:10 97:20 107:18 120:10 120:11 123:6 149:21 150:15 151:14 152:7 153:20 154:3 155:15,21 179:5 180:5 191:7,10 262:6 274:22 280:14 281:3,8 293:13 320:24 323:9 329:24
placed 139:22 141:12 251:21 265:21 270:15 274:12 287:12
places 140:21 141:9
placing 207:19
plain 153:22
Plaintiffs 2:5
play 61:21 100:17 331:10
Plaza 2:14,19
Pleasant 2:4
please 13:17 14:12 15:17 50:22 51:11 88:2 106:17 220:20 251:3 296:10 307:17 316:6 332:3 334:3,8
pmannix@ma... 3:15
PMP 315:10 316:4
point 37:13 38:6 42:10 48:4 55:16 58:13 59:19 64:11 70:21 71:1,23 81:24 103:1 106:6 108:6,12 117:14 123:5 139:7 162:19 163:19 170:9 177:13 180:3 184:4 193:1 199:10 209:4 210:14 213:4 237:11 242:24 256:23 257:3 286:11,18,20 294:15 307:10 314:18 329:12
points 242:19
police 257:13 258:18 259:14 259:15 260:11 264:6 301:19 302:22
policies 309:2
policy 106:13,16 106:20,24 107:1,4,6,9,23 108:1 280:13
POLSTER 1:6
Polytechnic 31:15
poorly 247:24 248:10,21
Port 26:12
PORTER 3:18
pose 235:8
position 20:23 25:6 57:7 88:20 129:7 229:24 230:2 296:23,24 297:1 311:17 326:21
positions 59:5
possess 306:15
possession 21:11 44:20 91:22 233:16
possible 148:3 240:11
post-impleme... 244:12
potential 51:7 51:18 92:8 167:23 232:2,5 236:20 269:18 269:19 321:19 329:13 330:2
potentially 262:22 269:18 320:24
PowerPoint 23:4 64:18 72:24 76:24 117:6 121:2 174:4 294:6
practice 28:15 75:9,15 76:4 79:8 155:17,23 156:4 157:2,22 158:2 162:5 169:1 170:7 190:9,17 203:9 203:17,24 213:5 216:16 231:10,20 232:3 243:16 243:17 273:2 288:8,11,15

323:18,19
practices 67:12 67:13 72:15 97:15 142:9,14 221:3 228:10 233:3,7
practitioners 67:5 155:10,11 156:20 222:6 301:19
precise 188:20
predates 281:21
preliminary 252:2
preparation 17:18 39:17 49:17 57:12 60:16 65:11 73:3 142:17 234:7
prepare 70:8 121:7
prepared 73:6 121:2 183:20 227:15 228:21
prescribing 199:23,23 291:20 322:18
prescription 1:6 13:10 165:19 171:11 172:17 173:7 298:10 299:5 315:9 316:18 322:20
prescriptions 298:12 299:7
present 4:5 26:10 118:16
presentation 64:19 65:7,17 65:22 70:4 73:6 117:7 119:11 121:14 129:1,4 294:7
presentations 23:4
presented 57:5 65:17 78:24 121:3,8,9 294:9 323:23
presenting 65:22 66:17
presently 321:15
president 15:23 26:4
presumably 75:20
pretty 63:13
prevent 75:7,14 76:2 79:7 229:13,24 270:16
preventing 173:17
prevention 317:18
previous 112:23 113:5 116:16 146:6 166:23 243:14 316:13
previously 166:19
primarily 40:22 52:6 61:18
primary 27:9 29:3 49:21 50:9,12 52:9 94:23 97:12 103:10 139:7
principles 238:6
prior 18:14,15 62:11,14,15 103:18 105:10 111:7,14 125:5 156:22 176:14 181:6 182:8 183:3,4 191:3 202:20 212:16 212:19 214:10 214:19 243:18 269:24 271:17 273:19 274:12 289:11 299:10 302:23 316:4
priority 110:14 114:12 122:15 122:23 123:7 123:11 124:21 125:12
private 27:14 28:21 288:8,11
Pro 245:11,17
proactive 134:3 135:20 307:18 310:6,11 331:6 331:11
proactively 136:17 148:11
probable 304:9
probably 18:17 29:7 39:1 45:1 86:20 99:13 139:15 165:13 265:3 306:1
probation 298:9 299:10
problem 165:19 171:12,22 172:1,6,10,18 173:8 227:16 228:22 263:3 322:22
procedural 5:21 9:10 39:13 40:11,15 241:15
procedure 75:14 139:12 143:17 143:22 145:2 145:23 150:2 150:20 151:1 152:8,17,18 153:16 154:7 198:13 199:14 246:1,4,11,17 250:7,12,14 251:7,8,8,16 251:22 252:1 255:13,17,18 257:18 258:12 259:18 266:22 267:13 280:13 281:2,13,14,19 282:10 283:5 283:14 284:7 284:14 285:8 285:14 295:9 302:17 329:1
procedures 9:13 11:12 38:16 85:16 97:15 150:7 151:20 152:1 164:11 185:3 187:17 187:19 191:1 232:17 233:11 241:6 242:15 250:5,10,24 251:2,11 255:19 260:17 290:23 309:2
proceed 311:8
proceeding 291:13
process 15:4 62:3,6 72:20 84:12 85:5 86:19,20 98:12 100:6,8,16,18 139:12 140:10 149:21 150:15 151:11,12,13 151:16 152:6 152:13,15 153:1,19 154:2 154:8 155:15 155:21 156:5 157:1 158:23 160:15 163:21 167:9 182:23 183:19 192:10 196:20 208:4 209:4 212:11 224:10,15 240:3 244:1,5 244:12,15 253:13 259:11 266:18 268:15 269:20 273:5 273:15 274:9 274:15,20 275:2 279:11 288:17 292:8 292:22 299:9 299:14 307:18 309:14 310:6 310:11,11 327:18
processed 326:14
processes 6:15 151:21 152:3
produce 22:18
produced 23:19 24:6 39:11,15 55:5 165:6 176:3 210:11 271:13 275:19 294:7
product 21:22 21:23 22:1 139:21,24 140:14 154:23 155:17,24 156:23 162:12 162:12 178:21 184:8 307:22 321:13 322:21 325:3 326:2
production 12:8 24:18
products 16:5,6 16:7,19,21 27:14,15 40:24 67:4 75:8,15 76:3 79:7 106:15 122:17 140:8 154:22 155:13 156:17 156:18,21

315:11
products' 180:1
professional 1:18 55:17 326:15 333:13
program 5:21 33:21,24 34:5 34:8,13,15 39:12 40:10,13 40:15 43:16 53:16 61:22 73:20 79:3 85:9 87:20 94:3 95:10 96:22 97:5,21 98:8,14,20 99:3 100:1 103:14,17 111:8 119:18 149:12,19,19 193:17 248:18 315:10 316:19 320:9 321:23 331:12
programmer 105:2,5
programming 83:8
programs 53:21 66:6 68:19
project 30:11 62:18 73:8 74:22 75:4 81:18 82:4,8 82:11,13,22,23 83:2,10,14 84:3,6,18,21 99:20 117:10 118:19 119:6 119:17 121:11 122:7 123:4,7 125:8 138:24 139:8 178:23 179:13,20 240:2 241:8,11
projects 110:15 114:13 122:17 123:13
promised 312:6
promoted 38:24
promotion 37:6 37:17 314:20
prompt 272:24
pronounce 234:3
Proper 297:13
proposal 9:16 221:2,15 271:14 274:7,8 275:5,8
proposed 222:3
propounded 336:9
prospective 242:5 243:14 245:22 246:6 246:18
protection 16:6
protocol 300:5
provide 100:20 230:11 330:13 330:15
provided 72:1 129:1 200:20 241:16 262:18 300:3
provides 322:24
providing 316:11
psychological 92:24
Public 1:19 333:14 336:23
publicly 199:2
pull 105:13
pulled 70:2,6,7
purchase 230:12 297:18 312:5 324:24
purchased 289:19
purchases 189:2 297:21
purchasing 178:20 179:24 181:23 189:3 269:24 322:19
purge 105:16 107:24 109:3
purged 108:17 108:22
purging 7:7 105:7 106:10
purpose 107:4 121:22 125:7 125:12 142:5 165:16 171:8 174:15 276:2 314:24 321:11
purposes 51:17 70:3 184:20 204:22 230:15
pursuant 1:15 17:17
put 40:16 67:22 70:24 75:19,21 81:17 99:19 120:15 184:8 191:7,10 226:3 240:19 262:3 263:14 270:21 271:5 274:22 285:21 291:15 329:23
puts 68:5 294:10 294:14
putting 65:8 79:21 123:8 279:14 280:15

Q

QA 37:2
qualifications 249:7 325:19
qualified 180:6 192:15 196:1
quality 27:5,8 27:10,12,13 29:1 30:11,16 30:18,21 33:9 36:23 37:2,8 38:3,21 59:17 59:20 89:1
quantities 167:21 194:7 300:8
quantity 236:14
question 14:19 14:23 15:9 21:5 23:13 25:4 51:11 53:9 63:11,15 68:20 70:19 72:9 74:6 77:17 78:11,16 79:14 97:10 99:5 104:1,6 114:6 134:11 134:15,21 141:6 152:10 153:17 161:3 163:24 178:4 205:16 209:9 214:8 224:5 238:17 245:4 271:5 284:4 288:18
questionable 190:3,8,20,21
questionnaire 184:17,22 209:2 253:6 257:6,10 259:12 272:2,7 273:12 278:20 279:18 280:10 283:10 289:24 290:8,19,20,21 291:1 292:3,16 293:1,10
questions 12:14 14:7,10 30:24 95:13 105:22 332:1 336:8
quibble 180:9
quick 66:23
quicker 63:22 63:23 272:16
quickly 30:4 57:19 142:20 165:5
quoting 143:21

R

R 137:18 335:1 335:1
R-03.07 143:23 145:23
raised 155:1 221:11
ran 112:19 116:10 289:12 289:17
Randy 278:7
ranged 28:11
Rannazzisi 24:13 69:15 80:11 165:4,7 171:6 174:9 204:5,9 206:5 213:14 241:23 275:21 276:12
Rannazzisi's 213:12,12
reaches 146:15
reaching 105:18
read 69:21 118:24 195:20 206:10 278:17 281:10 333:9 334:3 336:5
readily 181:1
reading 69:16 126:13 166:18 193:1 204:9,13
real 322:22 323:9
realized 315:6
really 30:4
realm 302:19

Realtime 1:19
333:14
reason 57:2
122:22 131:1
263:10 334:5
335:6,8,10,12
335:14,16,18
335:20,22,24
reasonable
40:18 126:13
161:17
reassured 316:7
recall 20:1,3
27:23,24 38:22
41:4,23 44:7
47:18 48:5,22
50:7 52:7,8
53:23 54:14,15
65:8,21 69:15
70:13,17,18,24
71:12,19 72:1
72:8,11,18
73:2 75:2,3,10
75:17 79:4,6
79:10,12,20
80:2,7 85:5
86:9,14,16,17
86:23 91:16
93:14 95:1,4
96:19 97:17
98:9,11,16
100:2,3,4
101:1,5,7
103:20 105:18
105:20 106:19
106:23 108:9
108:19,24
110:24 111:4,6
111:16 112:6,9
112:10,14
113:2,6,9
114:17,24
115:2,9,11
116:20 117:2
117:11 123:23
126:20 127:7
128:5,8,13,16
128:19 129:3,5
129:11,16,18
130:2 135:22
135:24 139:1
139:13 156:3
158:12 163:13
163:15 164:1,2
164:5,6,9
165:22 166:19
166:23 167:8
172:5,11
178:22 179:8
181:19 190:9
190:14,18
191:6,9 192:6
192:9,17 193:9
193:21,23
194:7 195:4,5
196:20 197:10
197:13 200:16
201:24 202:7
202:23,24
204:10,12,13
204:15 207:24
209:18 217:17
222:12,14,16
222:21,24
223:4 224:6,7
224:13 225:3
225:10,17
226:4,8 228:16
233:2,6,13
234:12,16,20
235:11,15
237:10,13,15
237:23 238:1
243:8,22 246:9
248:15,23
249:17 250:9
250:16 251:9
252:17 253:11
253:12 259:2
262:11 264:2
274:2,3,6,13
274:19,21,24
275:4 276:7,9
276:14,16
277:9 278:10
279:22,24
285:20 286:15
288:6 293:12
298:1,3 302:13
304:14,16
305:3,10,16,17
305:20 311:16
315:23
recalling 73:15
recalls 46:11
receipt 202:3
211:20 297:16
334:17
receive 34:9
156:20 279:19
received 71:13
109:12 123:17
138:17 161:15
161:20 165:10
170:18 173:21
174:7 175:16
185:17,24
186:12,14
206:5 232:21
275:22 276:1
276:19,20,21
285:9 304:20
326:19
receiving 124:2
211:21 251:9
255:11 277:11
298:19 299:17
recipient 138:18
recite 177:6
recites 176:6
recognition
227:16 228:21
recognize 89:24
recognized
130:8,16 323:3
recollection 48:2
69:20,24 73:22
74:8 77:12
78:2 80:24
83:24 86:8
94:14 97:19
98:18 111:22
114:15 119:15
140:12 146:8
146:17 148:10
179:20 246:2
260:1 272:6
273:23 319:9
recommend
200:20
recommendati...
9:8 75:11,18
79:24 80:3
158:21 159:6
159:10 164:1
190:23 192:18
194:8 195:9
200:11 201:2,7
203:2,6 223:2
224:2 331:4
recommendati...
73:11 112:20
116:11 163:14
163:16 164:2,3
164:6,8 223:7
223:8 232:14
234:11 236:23
237:4 242:12
242:13 247:17
249:9,11,15,18
290:3
recommended
77:13 149:11
149:16,18
154:12,15,17
154:19 156:15
156:24 158:2
158:24 196:21
202:16 211:9
211:13,14,19
233:4 236:10
237:18 330:11
recommending
162:19 331:9
recommends
162:8
record 13:2,15
57:18 88:5,8
106:16 107:9
107:23 108:1
137:10,15
186:3 219:24
220:3 227:12
296:11,14
332:5 333:6
recordkeeping
106:14 235:4
297:13
records 106:18
107:24 108:17
108:21 109:3
263:6,13
red 71:15
237:10,13
refer 82:23
120:20 170:10
189:22 194:17
reference 49:24
69:11 80:5
106:13 116:9
125:4 174:23
220:14 225:6
226:2 232:19
256:20,23,24
referenced
103:13 122:4
145:3 180:13
281:23
references
138:22 258:16
referred 69:13
174:4 241:21
248:4 269:13
referring 40:19
51:6 108:7
179:17 209:4
210:15 215:10
242:11 258:11
refers 69:2
240:12 250:5

reflect 82:3 83:9
reflection 81:13
reflects 83:6 122:12 123:5 157:19
refresh 80:24 111:21 119:15 146:16 179:19 272:5
regarding 153:18 191:18 234:10 243:13 248:3 278:14 299:20 302:9
regardless 42:24
regards 235:8
regionals 221:23 228:8
Registered 1:18 333:13
registrant 68:8 68:13,24 69:14 90:5,10 158:16 158:20 174:22 176:10,12 207:20
registrants 68:16 80:11 132:2,7 176:13 187:8 188:22 242:4
registration 132:4 142:1 195:2 197:2 198:11 204:7 204:22 205:6,8 205:20 213:15 213:21 214:13 215:3,9 300:7 300:14 301:3 304:12 306:13
registrations 194:3,13 195:7 197:15 260:6
regression 322:16
regular 101:15 104:3,4 139:17 327:1,9
regularly 127:13
regulation 68:12 68:22 165:23 175:4 176:9
regulations 6:18 40:17 106:12 142:7,13 164:21 187:6 188:21 241:17 294:13
regulatory 11:10 15:24 17:2 21:2,14 22:12 26:18,19 29:10,19,22 31:7 35:24 36:2,7,9,16 38:24 41:8 42:3,11,16 43:19 44:9 45:10,11 46:7 47:14,21,23 48:17,20 49:4 50:11,16,19 51:2,22 52:15 52:19 54:5,8 57:22 58:23 60:8 61:7,15 61:21,24 62:24 63:7 86:5,12 88:17,21 89:4 89:12 90:24 91:8,19 92:10 92:13,21 93:4 93:13 94:1,12 95:11,16,20,24 96:7,14,23 100:9,22 102:1 102:21 103:6,9 105:16,23 106:2 107:21 108:3,11,12 109:23 110:15 110:22 114:13 114:22 122:17 122:23 123:12 124:8 129:19 130:1 135:13 138:4,7,10,12 146:18 165:12 173:22 175:18 185:9,16,22 189:6 196:13 196:16 201:12 201:22 202:12 202:18 203:10 204:17 209:24 212:3 216:24 218:4 219:6 224:3 229:20 232:23 234:13 237:16 244:19 245:7 247:24 248:5,20 256:18 257:8,8 257:20 258:2 258:19 259:7 259:16 260:21 260:21 261:2,9 261:22 262:2 264:8,13 267:3 271:23 275:23 287:6 288:2 290:18 292:14 294:4 299:22 302:16,19 303:5 305:23 307:13 314:2 314:18 315:22 316:15 317:3,8 317:11 319:1 320:1,3,19 321:2,5 322:10 323:15,24 325:2,15,20 327:1,20 328:3 328:9,11,16,23 330:9,10,21 331:4,6,10
regulatory's 244:21 302:19
Reid 45:17
reinstate 310:7
reinstated 214:13 215:1,4 215:6,9,17,18
reinstating 308:2 310:1
reiterate 165:16 166:12,14,24 171:9,16 174:15
reiterating 171:18
reiteration 167:9
relate 21:14 109:4
related 16:19 22:2,5,11 42:12 44:20 53:20 211:16 215:21 277:14 321:18
relates 40:23 68:1 90:3 293:22
relating 36:18 38:9 283:8 302:24
relation 155:17 155:23
relationship 138:5 177:14 196:17
relationships 248:10
relative 20:23 21:13 29:14,19 31:3,7 36:16 38:14,16 42:17 48:2 50:5 60:18 71:3 72:14 73:19 89:15 95:9 96:21 134:5 251:10 330:16
release 250:7,12 250:14 251:2,7 251:16 255:23 288:13,21 322:21 325:4 325:19 326:2 329:2
released 157:13 159:2,17 161:17 252:22 257:7 287:20
releasing 280:21
relevant 90:18
reliant 248:1
relied 37:19 162:14 163:3 226:17,24
rely 163:9 205:19 207:18
relying 101:24
remain 154:14 232:11 291:18
Remaining 294:17
remains 159:14 162:17
remember 41:24 48:11 52:10 86:23 97:23 115:14,16 138:12 179:14 204:4,8 207:22 241:22 277:5 280:2,4,5 285:23 302:6 304:23 319:15
remind 276:3
Remondino 104:18,20
Remove 88:2 137:8 219:22
rep 273:11
repeat 68:20 70:19 99:6

114:5 141:5 150:12 162:20 196:10 238:16
rephrase 14:14 21:7
report 45:24 46:5 53:3 59:18 60:4,24 90:13 114:9 122:10 123:14 138:16,21 144:11 157:17 157:19 174:21 188:16 191:16 191:17 239:22 240:24 246:16 265:14 289:15 289:22 296:3 311:23 312:10 316:22 317:17 319:11,14
reportable 311:13
reported 45:21 46:14 47:20 57:23 59:11,13 59:14,21 60:4 60:11,13 94:17 109:20 113:15 115:4 117:8,23 124:5 126:6,8 126:9,10,11 136:4 143:19 145:14 156:3 158:3 188:15 188:19 265:15 267:23,24 270:7 310:5 321:4 328:10
reporter 1:18,18 1:19 13:16 14:17 333:13 333:14,14,22
reporting 61:6,9 106:7 108:15 109:4 125:7 129:10 134:9 134:20 135:5 135:19 147:2 150:9,22 151:4 152:5,9 158:5 158:23 159:7 174:24 187:6 251:7 269:22 270:2 310:3 314:3 315:19 316:17,23 317:12,16 328:17
reports 147:7 150:13 157:15 255:12 315:10 316:3,6 317:13
represent 23:24 83:16,19 225:8
representative 273:1
represented 46:13 221:20
representing 2:5 2:11,16,22 3:5 3:11,16,22 177:20 240:6 249:2 281:7
reproduction 333:20
Request 12:8
requested 262:19 263:8 279:18 283:10 300:3 333:7
requesting 190:5,12 326:6
requests 105:12 262:14
require 105:11 135:12 176:10 245:14
required 22:19 27:20 189:4 194:14 198:24 202:3 253:5 293:10 314:5 315:9 316:3 329:4 330:19 331:5
requirement 70:11 71:11 105:15 153:6 158:16 207:15 271:20,22 315:17
requirements 70:21 71:2 109:5 158:8 159:8 164:12 189:1,6 235:3 235:5,14 292:3 293:23 316:18
requires 142:22 188:21 271:16
requiring 159:15
reserve 331:24
resignation 56:21,23 57:3 60:9 277:5
resigned 60:1,3 277:1
resolved 305:13
resource 97:1 106:3 132:19 133:7
resources 100:20 102:17 132:6 225:9,13
respect 47:3 48:7 57:24 58:4,8 59:1 62:21 70:12 87:19 96:8,15 107:22 120:12 173:16 300:17
respond 262:13
responded 106:9
respondent 306:6,10
response 79:13 106:5 133:13 220:21 253:20 278:17 279:12 299:20,21
responsibilities 21:2 27:7 29:1 29:14,18,23 30:14,15 31:2 31:7 37:4,12 38:14 46:4,18 47:3,23 48:1,7 48:20 50:5,15 50:23 53:20 54:10 57:24 58:4,8,24 87:10 95:8 96:8,15 107:22 165:17 166:7 166:20 171:10 174:16 247:21
responsibility 27:9 54:4,7 58:15 60:8 61:7,10,12,18 68:6,13,17,23 90:3 94:23 97:12 187:8 214:6 264:9 276:5
responsible 38:9 46:5,7,11,15 50:10 52:6 95:2,5 141:24 259:5,8
rest 198:2 310:15
restate 51:11 61:5 134:15
restating 142:21
restricted 300:9 301:10,11
restriction 75:22
restrictions 75:6 76:2 79:6,17 79:21,24 92:18
result 187:14 233:12 274:14 274:23 280:1 300:24 301:8 320:18 325:3 328:1
resulting 322:21
retailers 221:23
retain 20:21 103:8,11
retained 62:17 103:7 161:18
retention 106:16 107:9,23 108:1
return 159:18 273:18 334:15
revealed 327:1
review 1:10 9:10 18:23 19:20,22 20:4,17 23:10 39:16 60:17 65:10 100:15 142:5,16 146:12,14 148:3 149:11 149:18,21,24 150:3,15,18 151:1,14 152:13,15,23 153:7 154:3,5 154:20 156:16 156:22 162:9 162:16 163:6 163:11 178:19 181:1,9,17,22 182:7 208:8,13 208:16 221:17 222:4,8 231:17 234:6 241:16 248:17 250:7 250:12,13 251:2,7,15 252:3,5,10 253:13 255:23 256:3 257:8,12 258:17 259:6 259:14 260:10

266:18 268:15 269:20 270:5 280:1 282:5,14 283:21 284:19 288:17 292:9 292:21 293:6 315:4,5
reviewed 20:10 20:13 22:23 74:16 143:14 144:5 154:13 154:18 159:13 161:16 224:2 247:12 309:5 326:7,11
reviewed/rele... 278:22
reviewing 139:11 149:5 179:22 189:3
reviews 163:18 163:22
revised 85:17 185:4 192:1
revision 40:4
revoked 213:6,7 214:12,23 215:5,8,15,16
Rice 2:2 14:6
RIGBERG 3:19
right 24:12 25:13 26:15 30:2 33:5,7 36:21 42:9 44:6 45:7 47:1 49:16 54:18,21 56:3,13 57:19 58:19 65:6,18 66:15 69:9 72:21 73:5 74:19 77:22 78:22 79:23 84:17 87:6 88:2,19 89:2 97:10 107:20 109:17 117:4 118:1,24 120:14 121:1 121:16 122:9 122:21 124:16 125:23 126:12 128:10 129:21 130:7 146:10 148:13 149:19 149:19 150:22 151:21 152:4 152:12,14 154:11 160:17 163:12 179:15 182:10 183:14 184:5,10,13,21 184:23 185:13 185:15 188:7 188:12,17 189:18 194:24 196:7 198:19 210:20 213:23 214:3 216:19 219:22 240:1 241:22 242:10 245:10,19 252:5 253:21 255:7,14,16,19 256:12 264:18 265:16 267:17 267:21 269:11 270:14 277:4 282:21 285:17 286:1,19 287:9 287:10 294:1 322:6
Rising 26:5
risk 28:15 222:6 320:24 321:17 324:13 325:4,8
Road 15:19
robust 232:12 299:2
Rock 15:19
role 29:3,5,10 37:4,7 42:2 49:2 61:20 100:17,19 139:5 165:12 173:22 227:18 228:24 230:4,4 244:21 275:22 331:11
roles 21:13 36:16 51:1 248:21
rolling 37:10
Romano 58:7,12 59:20
Romeo 319:8,17 320:1 322:8
Ron 66:3 117:15 237:17
Ross 2:8
routine 315:3
rule 291:5
rules 243:16
RXR 2:14

S

S 5:12 6:2 7:2 8:2 9:2 10:2 11:2 137:18,18 137:18
Sadler 49:20 50:3
Sadler's 49:21
safety 227:13
sale 156:23 176:15 315:13 316:24
sales 67:19 272:24 278:15 307:20 309:10 314:3 315:7,11 316:11 328:12 328:17
sat 18:6,10
satisfied 292:21
satisfy 221:6 291:12
satisfying 173:15
save 186:18,18
saw 24:6 87:14 98:22 103:12 136:4 148:18 187:13 213:11 267:17
saying 83:23 106:10 151:10 153:6,13 193:24 198:5 249:8 269:15 278:14 308:14 314:24
says 26:3,18 33:19 41:9 56:14 70:21 75:6 76:1 77:3 77:7,23 81:17 82:21 84:7 110:9,11 111:18 113:19 114:19 119:6 121:10,15 122:19 125:2 125:17 128:23 135:8 141:7 142:4 143:8,17 144:7 145:8 147:24 148:2 152:18,22 170:11 172:13 174:8 176:9 178:18 187:11 190:3 191:23 195:14 216:21 217:9 220:20 221:14 227:9 229:4 234:24 241:16 242:12 242:24 245:10 246:19,21 249:5 250:6,22 253:10,14 254:6,11 256:6 256:7 258:21 258:23 259:22 259:24 260:10 265:9 267:1 270:15 271:13 271:16 283:5 283:21 285:14 286:10 287:11 289:8 291:16 298:5 304:7 305:12 307:16 316:1 320:10 320:12 321:10 322:22 326:1
SB's 299:19
schedule 51:16 92:6,14,22 93:6,9,11 259:11 306:8
scheduling 92:5
Schein 2:11 4:6 5:16,17,19,20 6:6,8,12,17,19 7:6,9,12,16,18 7:21 8:6,8,11 8:12,14,17,20 9:6,9,10,12,15 9:17,20 10:6 10:10,12,16,20 11:6,8 17:1,2,6 17:7 20:22,24 21:12,13 23:6 23:17,19,20 24:2,11 26:17 28:18,19 32:21 32:24 33:3,8 33:10 35:4 36:15,22 37:20 39:11,16 40:10 40:24 41:7,19 47:12 51:14 53:22 60:18,24 61:23 62:11 63:2,7 67:2 68:16 69:3,6 72:2,13 73:18 74:11 77:8,23 81:8 83:20

86:5,12 87:11 87:18 90:12,19 91:9,20 92:22 93:5,13 96:17 100:1 106:20 107:3,5 109:13 111:8 112:2 116:22 117:10 118:18 119:19 121:21 126:15 128:2 132:19 135:16,22 136:6,17 138:22 139:20 142:12 143:8 143:24 144:20 145:16 150:8 154:2,21,23 155:20 159:20 165:6,11 169:2 169:12 170:2 170:22 172:19 172:23 173:23 174:8 175:18 176:3 177:13 178:8 182:2 187:15,18 188:13 189:4 190:23 192:13 195:23 196:23 201:1,15,18 203:11 204:18 206:7 209:12 212:10,18,19 212:22 214:15 214:16 215:19 218:7 222:1,19 223:1,5,9 224:9,14 226:10,12 228:14 229:21 229:23 233:5 234:15 245:20 246:3,15 247:18 262:19 263:15,16 269:22 271:12 275:10,19 277:13 294:21 296:21 297:23 299:4 300:1 301:8 302:1 303:14 304:10 305:2,5 308:17 309:1 310:20 311:23 314:3 315:6 316:2,5 316:10,16 317:1 320:24 323:15 325:16 326:5 327:5,16 328:24 330:12 331:10,12

Schein's 37:11 38:4 66:19 77:4 80:20 87:19 111:3 145:22 155:8 169:22 190:17 191:1 192:1 208:17 222:16 268:23 269:21 306:22 310:10

Schein-DiBell... 17:10

Schein-DiBell... 109:9

Schein-DiBell... 127:5

Schein-DiBell... 137:24

Schein-DiBell... 164:24

Schein-DiBell... 171:2

Schein-DiBell... 174:12

Schein-DiBell... 175:24

Schein-DiBell... 186:8

Schein-DiBell... 191:13

Schein-DiBell... 220:7

Schein-DiBell... 25:19

Schein-DiBell... 225:21

Schein-DiBell... 233:23

Schein-DiBell... 239:18

Schein-DiBell... 249:22

Schein-DiBell... 271:8

Schein-DiBell... 275:17

Schein-DiBell... 277:22

Schein-DiBell... 286:6

Schein-DiBell... 293:18

Schein-DiBell... 297:6

Schein-DiBell... 39:6

Schein-DiBell... 303:20

Schein-DiBell... 307:4

Schein-DiBell... 313:21

Schein-DiBell... 318:18

Schein-DiBell... 55:2

Schein-DiBell... 64:15

Schein-DiBell... 76:13

Schein-DiBell... 89:19

Schein-DiBell... 89:20

Schein-DiBell... 93:20

schematic 302:17

scheme 45:10

Schiavo 46:19 109:17 126:5 234:5 250:3,21 255:11 278:13 307:8,9

Schmidt 46:23 50:1

SCHOLER 3:18

school 32:16 33:11,14,20 34:4,18,20,22 35:1,16

SCOTT 2:8

screen 206:13

scrutiny 327:20 328:3

se 43:17

search 252:7,7,8 252:8 253:1,17

second 149:20 150:14 152:10 153:11 157:19 193:4 207:12 240:12 253:17 258:1 266:19 267:10 278:6 324:21

second-to-last 282:23

secondary 326:4

section 207:15 230:20 231:1

security 194:4 197:4 227:14 227:20 229:1,7 235:3

see 32:5,11,14 39:24 40:6 84:15 90:15 121:5 128:3 139:18 144:8 148:23,23 149:15 165:15 165:21 166:23 167:16,18 168:9 173:11 173:18 174:23 175:11,15 187:21 188:19 190:22 191:4,5 196:3 199:17 203:12 204:21 206:16 211:7 212:7,9 230:24 235:19,20 236:1,3,14 240:24 241:3 242:8,22,23 249:6 251:18 256:10 257:3 257:14,15 259:14 263:6 276:11 282:19 292:15,20 302:22 303:16 307:17 308:2 310:15 319:2 320:13

seeing 129:3 179:8 248:13 272:11 290:13 291:11 296:2 303:15 319:12

seek 168:9

seeks 214:14

seen 49:16 244:9

segment 178:20 179:23 323:18

selected 139:8 154:22

self-certificati... 222:10 224:9

self-medicate 307:23 308:15 309:12 312:6

self-medicating 307:19 308:24 309:3,9 310:21

311:12,17 312:11
sell 310:22
selling 27:17 238:11
seminars 42:23 43:5 44:1,17 44:21 66:4
send 160:15 161:7 220:22 251:4 253:18 257:9 273:11 274:11 279:15 279:20 283:5 283:22 284:8 284:20 307:21 310:2
sending 274:15
sends 287:8
senior 30:10 41:7
sense 199:5,7
sent 18:22 80:5 159:15,22 252:23 253:7 278:8 281:20 283:2 287:4
sentence 115:12 193:4 229:3
separate 51:1 52:14 108:4
September 55:24 56:21 73:8 79:3 83:15 87:2 116:13 117:7 118:17 119:17 119:22 125:6 138:21 142:11 154:1 159:21 165:5 179:13 275:13
Sergio 46:1,6 48:14,18 49:3 50:9 60:10 76:22 100:22 101:2,24 102:18 103:4 103:23 106:5,9 109:17,22 124:4 126:4,7 126:9 128:3 218:20 220:12 220:14,18,24 222:13 234:6 250:22 264:17 278:13 281:20 294:2 304:7 307:11 313:17 313:18 314:17 319:7,16,18,18 319:23 322:7 324:21 328:8 331:9
Sergio's 58:21
serious 172:17 173:8 235:8
serve 133:7
service 3:16 221:22 247:22 248:19
services 1:21 13:4 67:4 234:21
servicing 294:23
session 186:24 187:1,3
sessions 44:22
set 75:6 76:2 79:6 95:16 108:2 110:21 111:19,24 113:17,17 114:21 115:6 124:7,12,14,20 125:9 126:16 126:16 136:11 143:14 144:5 198:10,22 208:21
sets 67:23 179:12
setting 107:22 136:9 140:2 216:5
settlement 305:13
setup 84:12 208:5 251:8
Seventh 3:9
severe 92:18,24
sexual 291:22
SHAPIRA 3:13
share 133:7 261:12
shared 125:24 170:17,22 258:13 327:4,8
shares 122:5
Shaun 20:2,3,5 52:5,8 73:16 279:14 286:11 287:2,11 289:8 289:9,12 307:8 308:12,21 309:8,18,20,24 310:4 311:22 312:9,12
sheet 334:7,9,12 334:15 336:12
shifting 59:4
shipment 191:3 251:20,23 265:21
shipments 40:20 270:16 300:11
shipping 235:9 271:18 273:19
short 32:6 88:6 220:1 279:3 280:20 282:12 289:10,20 296:12
short-term 330:11
shortcut 23:23
Shorthand 1:18 333:13
show 17:12 39:8 55:4 64:17 65:2 76:15 104:9 109:11 138:2 178:3 191:15 220:9 225:23 239:20 249:24 263:15 271:10 286:1 293:20 298:18 303:22 313:23
showed 24:1,17 24:17 297:18 327:24
showing 78:20 78:23
shows 32:20
SHUBBA 3:9
Shubbaharris... 3:11
Siebel 272:19,22
sign 333:9 334:8
signed 72:13,16 171:5 174:9 202:1
significance 78:4
significant 139:23
significantly 133:17,22
signifies 73:15 73:23 81:24
signify 74:16 81:19
signing 334:10
similar 207:14
simple 205:17
simply 17:16 28:21 80:23 163:24 196:5 207:18 227:2 245:5 310:7,20
sir 14:3 331:19
sit 54:13 74:19 75:2 98:17 112:8 122:22 148:9 219:11 249:14 275:3 280:3 305:18
site 210:12 257:11 259:6,8
site's 131:14
sitting 120:18
situated 229:6 229:11,17 230:7
situation 216:22 291:8
situations 248:3
six 22:24 139:24 288:22 298:11 299:6
size 67:20 91:2 143:2,12 144:3 146:21 147:4 147:15 148:13 149:14 175:6 177:8 178:9 181:19 188:23 238:5,20 239:7 267:12,19 268:22,24 269:4,16,23
sjones@lockel... 2:11
slide 67:22 73:5 75:1,6,20 76:7 79:9 81:17 174:5
Slides 6:13
slow 14:15
small 228:7
Smith 198:16
snapshot 25:21
social 194:4 197:4
sole 68:13,17,23
solely 144:20 145:16 326:3
Solutions 3:22
SOM 9:10,13

82:4,11,22,23 82:24 83:2 84:5 98:3 99:20 117:10 118:18 119:6 119:16 122:7 178:23 179:13 179:20 240:2,3 241:6,7 247:20 250:5 251:11 255:12,19 257:17 321:23 331:7
somebody 23:17 64:10 122:6 280:20 282:1 282:13 288:20 298:16,19
somewhat 233:1
SOMs 77:4 86:9 86:10
SOP 144:7
sophisticated 229:4 301:15
sore 28:7
sorry 28:2 32:9 32:12 63:16 77:17 150:11 156:9 170:4 204:11 220:24 240:5 254:2 275:8 319:24 320:4 322:1
sort 53:14 67:23 73:1
sought 57:6
sounds 107:20 316:21 317:5
South 2:4 3:9
space 334:6
speak 18:15 20:6 73:18 74:12 308:20
speaking 28:15 128:18 300:22
specialist 47:21 48:17
specialty 110:23 114:23 124:9 178:20 179:24 323:19
specific 35:24 41:23 48:22 69:20 71:6,10 75:17 80:2 86:24 91:16 100:4 103:19 105:20 111:4 145:9 163:16 164:7 170:10 189:1 195:3 237:23 249:17 253:12 276:9 280:2 298:3 304:17 320:22
specifically 72:4 72:10 86:16 101:4,6,8 106:23 121:18 130:5 175:4 232:18 233:6 234:17,23 241:21 250:16 278:11
specifications 8:9 85:3 176:5
specifics 72:20 88:13
specifies 143:23
specs 184:15
Split 15:18
spoke 18:11,14 19:9
spring 272:6
Stader 278:7
staff 114:19 143:14 144:5 149:23 150:17 154:5,9 192:13 195:23 246:24 247:4 252:14 258:14 277:17
stage 53:1 73:23
Stan 296:18 297:9 299:18
stand 47:7 88:2 234:17 296:9 332:2
standard 27:13 30:18,22,23 38:15 75:13 85:16 130:3,17 143:16,22 145:2,22 150:1 150:7,19,24 151:20,24 152:8,16,18 153:15 154:7 164:10 185:3 187:16,18 198:12 199:14 233:10 245:24 246:4,10,16 255:12,18 283:13 284:7 290:22 295:9 328:24
standards 31:9
standing 298:6 298:17
Stanley 296:17
start 45:24 55:20 74:22 75:4 79:2 80:24 88:14 104:13 108:8 110:20 114:20 124:6,13,18 220:13 259:9 259:11 278:6 318:13
started 17:6 24:23 29:4 32:16 33:11 73:8 81:19 82:22 83:14 84:6 89:13 94:9,11 95:18 96:11 97:6 117:10 118:18 119:7,16 121:12 179:21 225:2 241:8 271:23
starting 83:22 125:8 179:14 278:18 289:21
starts 142:20 239:9
state 15:16 44:15 105:11 116:21 168:20 169:18,20,24 170:12,14 198:11 205:13 213:19,22 235:24 248:7 298:7 300:6,13 301:20 314:23 315:17 316:9 316:19 317:19 320:8 334:5
state's 315:9
stated 76:7 150:1,19 152:16 154:6 155:6 172:7 248:11 267:23
statement 51:20 60:6 68:21 69:2 86:10 89:23 113:5 114:1,15 115:1 145:9 146:6,23 155:20 197:18 219:12 227:22 227:24 228:5 228:20 283:12 284:5 298:24 305:2
states 1:1 6:20 29:24 36:12,17 92:17 175:4 245:14 247:16 **stating** 172:8 307:21 309:11
statistical 85:2,6 85:12 154:22 155:2 184:13 184:15 322:17
statistics 321:18
status 140:21 141:4,9,12 157:12,18 159:3 172:5 208:15,17 293:15
statute 71:6
Steele 304:2,3
Steffanie 319:20
Steffanie-Oak 58:14 264:18 264:19 294:1,9 319:8,16 322:8
stenographic 13:15
stents 28:17
step 160:14 161:6,13 198:10 253:16 253:17 255:3 256:14 270:11 280:22 281:22 281:24 282:5 282:14 283:1 284:16
steps 132:3 183:4,5,8 184:2
stick 15:15 120:17
Stipulations 12:11
stop 14:12 15:8 130:23 191:2 310:21
stop-shipment 134:4 135:20
stopped 64:2
strategic 35:20

street 1:16 3:3,9 3:19 13:8 321:21
strike 22:15 101:21 265:19
structure 45:11 59:6
study 35:15 139:20 140:8 150:3
stuff 267:5
subject 1:10 6:13 7:7 8:18 9:7,13,21 10:7 10:14,17,21 11:10 128:13 192:4 193:14 222:7 334:10
subjected 325:7
submitted 85:4 157:15 184:16 306:14 326:5
Subscribed 336:19
subsequent 162:20
substance 6:11 16:11 90:1 92:8,15,23 106:21 118:3 143:10 144:2 165:18 171:10 174:16 245:13 251:6 276:3 297:16 309:2 316:11 321:12 324:24 336:11
substances 8:15 16:9,13 21:3 21:15 29:15,20 31:3 36:19 38:10,17 41:3 42:12,18 43:1 47:17 48:3,3,8 48:24 49:8,10 49:13 51:14 66:2 67:9 68:1 68:5,9 70:16 89:14,24 90:6 91:12,15,23 94:10 106:14 106:18 130:10 134:9 140:3 142:21 158:7 159:9 167:22 168:12,14 170:1 174:19 176:8,16 187:9 191:24 192:3 192:16 194:5 196:2 197:6 200:22 202:15 202:22 203:14 204:24 212:6 213:17 215:24 218:7,15,22 221:19 227:18 228:23 229:8 230:13 232:6 235:9 236:6,6 238:11,23 239:11 243:15 270:17 273:21 276:7 277:12 277:15 289:20 297:13,21 298:20 300:10 301:8,13,21 302:24 306:13 307:24 314:4 315:8,14 316:24 320:22 320:23 321:2 322:20 325:20 326:7 329:3
substantial 91:23 221:12 294:11
substantially 91:3 143:3 175:7 177:8 188:23
substantively 18:7
successor 318:21
sufficient 187:19 243:2 243:11
suggest 113:16 167:17
suggested 211:5
suggestion 231:4
suggestions 232:16
suitability 202:14,21 212:5
Suite 2:9 3:3,9
sulfate 306:8,10
sulphate 306:15
summarizing 220:15
summary 7:13 7:17 127:21 138:23 139:19
Summit 60:20
supervision 333:22
supervisor 41:16,18,22 42:7 47:14,15 123:19 286:16 286:19,22 297:10
supplied 306:7 306:10
supply 16:13 110:22 114:22 124:8 227:15 227:19 228:24 229:5,15,19 230:3 261:13 277:12 297:22
supplying 304:10
support 12:2 100:20,23 102:1,17,20,21 103:2,4 229:7
supported 45:20 101:2
supporting 227:12
supposed 133:4
sure 21:4 23:12 25:3,5 51:12 53:9 63:10 64:8,12 68:21 74:5 78:17 95:14 100:21 105:10,14 114:8 134:17 139:14 141:7 143:20 145:8 146:22 150:13 160:1 169:8 203:19,20 204:1 219:20 224:17 230:5 238:19 277:3 282:21 286:13 286:16,22 316:16
surprising 295:22
suspend 301:6
suspended 214:13 215:4,9
suspension 132:21
suspensions 162:21
suspicious 7:10 8:9 38:14 48:22 51:7,19 51:23 52:13 53:3,15,21 54:1 58:1,5,9 61:14,17,22 62:2,5 63:4 68:8,18 69:7 71:9 73:7,19 74:21 77:8,12 77:24 79:2 80:20 81:18 83:13,20 84:8 85:8 86:2 87:20 90:5,9 90:13 91:1,5 94:2,15,17 95:9,22 96:21 97:4,20 98:7 98:13,19 99:3 99:24,24 101:11 102:10 102:23 103:14 103:17 104:7,7 109:13 110:13 111:1,7,20 112:1 113:18 114:11 115:7 119:18 121:11 122:14 123:10 124:20 126:17 128:12,14,23 129:2 131:1,16 132:17 133:10 134:5,20 135:6 136:10,12 139:11 140:21 141:3,9,13,20 141:21 143:1 143:10 144:1 155:2 157:11 157:12,18,20 157:23 158:3 158:19 159:1,3 159:12,14 160:7 161:7 168:10 173:16 174:18,21,24 175:5,12 176:4 176:11,14 177:7,16 178:11 181:9 184:14 185:2 187:7 188:14 188:17,18 189:19 192:1

193:16 205:22 207:19,21 208:3,7,9 209:14,22 226:5,6 241:15 248:17,22 250:9,23 262:22 265:1 265:11,22 267:16,18 268:14 269:5 269:16 270:2,5 270:6,12,13 276:6 289:23 294:12 301:16 320:8 322:14 322:23 323:8 323:17 324:4 324:15 326:24 329:11,22 331:11
sworn 13:21 333:5 336:19
synonymous 141:4
Syosset 15:19
system 7:10 8:9 27:11,13 30:16 30:19 37:9 38:4 58:18 68:7,14 69:1,6 69:7 77:9,13 77:24 80:21 81:6,14 83:21 84:9,15 86:3 90:4 94:16,19 94:20 101:5,11 102:4,9,11,16 107:16,20 109:14 110:13 110:21 111:2 111:18,22,24 113:16 114:1 114:11,21 115:6 119:20 119:21 120:3,4 120:7,8,9,11 122:15 123:11 124:7,12,14,17 125:9 136:11 140:6,20,23 141:3,8,10 142:6 143:9 144:1,20 145:16 146:19 147:3,8,10,14 148:6 149:1,16 149:24 150:18 150:23 154:6 161:19 163:18 176:4 178:17 178:18,24 179:4,5,17,22 180:4,7,11,13 180:15,24 181:4,22 182:8 182:9,11,12,13 182:14,16,18 182:20,21,22 183:6,18,23 185:7,12 188:14 189:8 189:10,15,20 189:24 192:2 194:14 211:4 214:17 233:5 242:17 245:17 247:20 248:22 262:6,7 263:16 267:6 268:23 269:21 270:15 270:19 272:20 274:5 299:3 301:4,5 306:17 306:21,22 308:4 311:23 315:19 321:14 322:15,24 323:1,8 324:5 324:16 327:23 329:11,23
systematic 182:3 182:4
systems 11:11 38:15 107:14 110:16 111:3 113:1 114:20 116:14,18 121:24 122:16 124:6 125:10 126:14 135:10 135:14 136:18 331:7
systems/proce... 301:17

T

T 5:12 6:2 7:2 8:2 9:2 10:2 11:2 137:18 335:1
take 14:17 15:8 15:11,11 33:24 35:24 42:16 79:19 87:7,24 110:13 114:12 122:15 123:11 131:14 132:3 137:7 160:3 200:10 201:1 214:5 219:17 220:20 225:13 280:12 296:7 309:8
taken 1:15 25:10
takes 64:10
talk 63:22 64:5 78:14 85:1 139:19 172:23
talked 18:7 107:12 142:22 165:3 184:7 293:24
talking 22:1 26:16 48:24 51:15 52:4 65:13,15 82:8 99:10 167:15 172:14 174:14 183:24 184:18 185:1 186:3 198:3 208:6 210:23 211:15 213:14 260:8
talks 79:1 80:19 84:2 90:8 115:12 121:18 174:20 231:1 251:5,16 281:13 297:14
target 300:2
team 58:19,21 59:21 95:12 97:8,11,17 100:21,22,22 101:2,24 102:3 102:8,15 103:5 103:9 109:16 110:6,7,8 122:24 140:11 140:15,18,19 141:23 146:12 147:15 185:9 204:20 319:4,5 319:14,15,19 320:13 322:6,7 322:9 323:16 324:22 326:3 328:8 330:10 331:5
teams 100:14 320:20 326:24
technical 102:21
technically 311:18
TECHNICIAN 4:2
techniques 330:17
technology 189:5,22
Tejeda 11:7 46:1,6 50:9 60:10 76:23 102:18 106:6 109:17 124:4 126:4 128:3 218:20 281:20 294:3 314:17 319:7 322:7 324:22 328:8 331:9
Tejeda's 101:24
telephone 4:6 192:13 195:23 256:8,11 257:1
TELEPHONI... 3:7
tell 26:1 37:3 48:15 49:20 63:10 64:22 191:19 206:15 216:13,13 272:14 279:16 303:11,14 313:8
telling 131:18 152:11 190:17
tells 204:6
Tennessee 297:23
Tenth 3:3
tenure 43:3,11
term 21:24
terminated 132:15 133:6,9
tested 85:7
testified 13:22 73:16 74:10 319:7
testify 281:12
testimony 5:4 14:18 18:8 19:22 20:5,7 20:10,11,14,15 74:1,17 180:19 268:10 333:6
testing 85:15 86:21 183:7
Texas 2:9

Thank 56:18 105:16 240:22 331:23
Thanks 278:24
they'd 270:21
thing 55:10 254:24
things 23:3 55:8 71:15 98:1 114:10 168:4,8 168:15 178:12 181:21,23 197:1,1 254:4 254:19 260:22 261:10
think 21:19 34:1 34:24 44:19 50:13 107:19 123:2 133:4 137:5 148:3,17 151:9 156:5 163:1 174:3 179:4 188:1 194:17 195:11 203:5,8 210:17 214:3 217:22 228:8 258:6 277:2 286:21 289:15 292:1 310:2 331:20
third 24:8 39:20 41:6 155:5 173:11 225:7 242:24 267:7 277:24
third-party 30:20 222:11 224:14,18
thirty 334:16
Thornton 58:23
thoroughly 131:2
thought 50:2 64:1,1 70:10 117:21,22 325:16
Thread 7:6 8:17 9:12,20 10:6 10:13,20
three 18:18 29:7 35:11 36:14 99:11 177:15 178:12 231:24 248:18 277:8 329:3
threshold 139:23 140:3,9 146:15 149:22 150:6,10,16 151:14 152:14 154:3 162:11 278:23
thresholds 95:17 111:19 112:1 113:17 115:7 120:5,12 124:20 126:16 136:12 140:13 142:8 143:13 144:4,21 145:17 149:24 150:18 151:1 152:15 153:10 154:6,12,17,24 238:4 321:13 321:14 324:23
throat 28:8
throw 63:20
TIFFANY 3:18
tiffany.ikeda... 3:21
Tiller 46:20 47:5 47:21 109:19 126:5
Tiller's 47:2
time 13:6 14:20 15:7 18:6,13 19:8,19 20:23 26:16,17 27:1 29:2,18 31:1,5 31:14,20,21 34:2 38:23 41:18,24 43:3 46:6 48:4,5,11 52:4,20 53:23 54:16,17 58:13 58:18 59:7,10 59:20 60:7,9 61:1 67:2,18 69:21,22 75:12 78:15 81:24 88:3,8 89:7 90:19 93:8,12 94:8 95:3,6,17 96:10,12 97:21 98:5 101:3,16 102:2,8,19 103:1,24 104:19 107:14 108:6,10 109:5 119:16,20 123:5 124:22 126:24 136:5 137:9,15 139:22 148:7 149:1 154:12 162:10 163:23 171:24 179:5 186:19 203:17 210:14 219:7 219:23 220:3 220:10 225:3 226:9 229:22 233:18 234:19 247:19 248:12 272:10 277:4 280:14 281:8 285:22 289:10 294:21 296:2 296:10,14 302:12 306:9 312:13 313:11 314:1 318:14 318:15 319:11 326:9 328:22 329:20,24 331:20 332:4
timeline 72:22 73:2 76:24 84:23 88:12 98:23 99:20 117:5 119:1 120:22 180:14 210:20,21 239:24 240:4
timely 300:4 316:3
times 279:17 280:8 281:24 329:3
timing 174:24
Timothy 10:22
Tina 58:14 264:17,19 294:1,9 319:7 319:22,24 322:7
title 6:20 15:21 15:22 16:23 36:23 89:3 286:13,17
titled 230:21
titles 252:21
today 13:12 14:7 15:13 18:23 19:6 26:17 39:17 49:18 54:13 57:12 60:17 65:11 73:3 74:20 75:2 98:17 103:13 142:17 148:9 219:12 234:7 249:14 275:3 279:16 280:3 305:18
today's 13:5 17:16 332:4
told 79:4 243:8 248:16,23 263:4 270:9 308:21 324:3 324:12 325:6
top 39:22 110:14 114:12 122:15 123:11 138:23 250:3 251:17 265:24 281:13
topics 66:23
total 306:7 328:12,17
Touro 33:6,11
track 188:22 227:11
trade 43:5,24 44:3,6,10 70:4 78:24 117:8,17 117:21 118:3 118:12,14 227:3 231:5
trafficking 212:17 214:11 215:12 218:5 218:10,24 278:3
trained 44:8 326:8,12
training 36:1 42:17,21,22 43:2,4,8,19,20 43:22 44:22 66:6 183:7,9 183:14 185:8 227:5 321:19 325:18 326:19 330:14,16
tramadol 315:12
transactional 108:17,21 261:13
transactions 109:4 316:23 321:12
transcript 333:9 333:19 334:17 334:19
transcription 336:7
transition 87:15 108:14 188:13

trapped 327:21
treatment 92:16 235:23
tree 312:8
trends 321:21
Trib 104:24 105:1,2,6,15
tried 228:8,9
trigger 299:19
triggered 148:13 178:11 238:4 239:6 265:16
triggering 51:7 300:15
trip 301:4
trouble 312:17
true 60:6 112:10 112:15 113:7 113:10 114:15 115:1,10 116:21 145:1 145:12 146:4,8 247:3 270:1 283:11 326:9 333:6
truthful 323:4
try 63:21 88:11 120:16 125:10
trying 24:21 63:19 78:19 82:17 112:24 116:17 120:15 121:23 318:14
turn 186:19 207:20 251:14
turns 218:22
twice 66:8
two 18:18 29:6 32:7,18 33:9 34:2 35:11 42:6 84:19 99:11 157:14 245:5,8 248:8 316:13,20 320:3 329:13 330:2
two-year 32:4
type 75:16 162:12 173:13 323:18
types 222:5 232:19 248:3 288:16

U

UL 30:15 31:24 33:8
unclear 70:11 70:14,21 71:2
underneath 45:22 58:11
underqualified 327:7
underreporting 315:7,15
understand 14:13 21:5 23:13 53:12 65:3 74:6 78:4 78:8,10 82:18 83:12 94:2 119:8 120:2 132:8 133:19 134:1 138:3 139:4 140:1,22 141:2 157:21 158:1 159:5 240:11 258:10
understanding 112:22 116:15 157:1
understatement 301:24
understood 14:24 25:3 90:11,20,23 115:24 135:7 142:10 285:2
underway 82:3 83:9 84:18
underwriters 30:5,8 32:3,15 36:5 55:17 328:11
undoubtedly 172:15
unify 228:9
unilaterally 280:21
unintentional 321:16
Uniondale 2:15
unique 229:23 230:6
uniquely 229:5 229:11,16,17
United 1:1 6:20 29:24 36:12,17 92:16
university 304:11 305:6 306:9,11,12,14
unnamed 133:3 133:5
unpack 113:11
untrue 112:10 112:15 113:7 114:1
unusual 91:2,4 143:2,4,11 144:3 149:14 175:6,8 177:7 177:9 188:22 188:24 190:1
USCA 6:21
use 28:14 91:22 92:16,17 97:2 166:11,13,24 172:16 173:6 180:8 200:24 211:17 229:16 245:11 308:1,3 308:8 310:9
uses 143:8,24
usually 327:17
utilization 323:20,21
utilize 322:16

V

vaccines 46:9 47:9
vaguely 69:17 226:8 274:24
valid 204:21 300:6,13 301:1 301:3,20 304:12 305:6 306:12
validation 86:22 242:16
validations 242:21
validity 323:4
variation 238:20
variety 167:21
various 23:5
varying 294:18 295:7
vast 210:12
vein 207:14
verbal 14:17
verbally 199:12
verification 61:19 94:22 95:5 97:11,16 102:8 103:5 105:23 110:4 140:10,15,18 141:23 146:12 147:15 198:7,9 198:20 201:14 209:20 216:4 219:14 243:5 247:12,14 252:5,18 253:5 253:13 255:5,9 256:14,18,21 257:24 260:9 265:11 270:20 271:4 283:4 285:3,5 290:12 291:11 292:8 292:21 306:22 306:24 312:13 312:18 316:22 317:14 320:13 320:20 326:3 328:11 330:15
verifications 11:11 50:24 51:9,17 52:1,6 52:12,18,21 61:8,10,16 86:5,12 94:21 95:2,14 97:1,8 100:10,21,24 101:3,19,23 102:3,15 104:22 106:2 110:6 122:24 138:5 148:18 149:7 185:9 202:18 204:20 205:4 217:1 218:18 244:20 244:24 245:6 247:5,23 248:20 252:3 257:1,21 258:20 259:17 260:2 261:23 273:18 274:4 280:21 282:2 282:13 283:3 284:2 286:12 286:14,19 287:5,7 288:12 288:21 299:23 300:5 317:2 325:1,7,17 326:14,20 330:13
verified 197:16
verify 170:6 231:18
verifying 141:24 260:13 293:14 300:13
version 250:8
versus 169:13

Vesey 1:16 13:8
veterinary 155:11
viable 162:17
vice 15:22 26:4
videographer 13:1,3 88:1,7 137:8,14 219:21 220:2 296:9,13 332:2
VIDEOTAPE 4:2
videotaped 1:15 13:7
view 133:16 165:18 171:11
viewed 262:22
violation 218:10 283:13 284:6 284:13
violations 249:11
Virginia 46:9
virtually 222:2
virtue 45:2
Visio 250:8 251:3
visit 8:12 138:24 185:24 209:1 210:13 222:2 223:10 257:11 259:6
visiting 222:18 224:10
visits 223:2 256:21 258:17 259:8
vitae 25:15
volume 221:24 287:17

W

wait 63:17 105:15
waiting 236:18 237:9
Walmart 3:11
want 21:4 23:12 30:4 45:24 55:10 72:20 73:1 74:5 88:11 143:20 165:4 181:13 208:2 214:5 216:6 299:4,9 320:16
wanted 25:3 105:9 218:14 263:5
wanting 218:6
wants 130:22 212:17 218:21
Washington 3:4 26:13
wasn't 31:20,21 111:13 118:12 118:14 160:20 181:15 189:8 213:10 253:4 315:24 329:17
watch 131:15
watching 64:10
watermark 65:18
way 55:24 63:7 71:5 87:8 104:15 112:9 133:22,22 138:3 151:9 157:7,8 167:13 176:19 181:24 184:3 206:13 209:9 213:20 254:13 284:24 293:5 309:13
ways 101:1 106:1
we'll 15:11,11 36:21 53:14 72:19 80:14 160:3 178:2 179:11 245:19 272:15 296:8 308:10 318:4 331:24
we're 26:16 64:23 65:14 143:21 180:9 208:9 210:23 214:3 266:7 268:19 269:20
we've 107:12 142:22 184:24 219:18 261:10
website 252:7,8 254:1,17 255:1 255:2 256:2 282:3,4 298:7
websites 199:4 284:20
week 18:1 220:16 277:1,7
week-long 35:12
weeks 18:18 19:2
weeks' 277:8
welfare 92:1
went 31:23 33:6 33:7 76:9 131:12 181:12 181:14 268:15 280:18 284:17 293:12
weren't 132:2
Wesley 60:4
whatsoever 29:14 31:2 36:2
white 291:9
wholesale 129:7 131:2
wholesalers 221:10
Wilburn 46:20 47:19,20 109:20 126:5
Wilding 110:5
Williamson 113:2 115:14 115:15,23 121:20 125:5
Williamson's 112:19 116:11
witness 2:12 12:5 13:18 32:23 53:7 56:6,14,17 63:16,24 64:8 64:12 74:4 76:9 78:17 81:11,23 82:21 102:7 112:5,14 113:22 114:5 117:1,14 120:1 123:22 125:1 125:16 126:20 127:11 129:15 129:24 130:14 131:10,23 132:24 134:14 136:23 141:16 144:15 145:6 151:8,24 152:22 153:4 158:11 160:11 161:12 163:1 164:15 166:4 169:8 172:4 177:2 178:1 180:20 183:13 188:1 189:14 192:24 193:9 193:20 194:11 197:13 199:10 200:15 201:6 202:6 203:5 205:3 206:1 207:9 213:1 216:3,10,15 217:5,22 225:16 237:3 238:16 239:15 240:7 246:9 247:10 252:17 261:20 262:11 263:1 264:1 266:8,13,15 268:12 269:8 273:8 282:9 283:18 284:13 285:13 289:4 290:11 291:4 292:7,19 293:5 295:16 296:1 298:23 300:21 302:5 303:8 305:9 308:7,20 309:17 310:14 311:6,16 312:23 313:7 314:10 317:23 321:8 322:4 323:13 324:10 324:19 325:12 327:12 328:6 328:20 329:8 329:17 330:5 331:1,17,23 333:5,6,8 334:1
witnessed 236:15
witnesses 19:23
women 291:23
word 79:20 166:12,13 167:3,5,11 168:24 169:21 171:15 180:9 180:10 229:16 254:5
words 83:13 120:15 123:8 208:17
work 21:22,23 21:24 104:16 116:8 244:22
worked 16:24 21:21 100:14 104:21 105:3

115:3 138:4 294:1,2 307:9 307:11,12 313:16,16,18 319:21,22,22
working 28:4 32:23 86:18 245:2
world 323:9
worldwide 27:17
wouldn't 25:5 139:16 141:16 148:16 164:15 166:4 169:16 179:3 205:7 229:14 257:22 264:24
wrap 296:8
Wright 128:18 128:20,24 129:6 135:17
writes 158:22 171:8 220:23 220:24 250:21 286:9 287:2,11 289:8 304:6 314:22
writing 278:13
written 71:6 253:19 317:8
wrong 76:10 82:13
wrote 68:11 104:23 179:7 289:12 299:17 299:18 309:24 310:4 320:1,2

X

X 5:2,12 6:2 7:2 8:2 9:2 10:2 11:2 33:24

Y

yeah 18:2,4 20:3 21:9 22:21 25:2 29:9 31:16 49:2 50:4 53:13 59:19 70:7,20 78:7 88:24 89:10,10 94:13 97:13 102:13 102:16 107:19 110:3,19,19 147:11 167:19 177:3,22 184:2 189:17 203:8 204:14 208:1 210:23 218:1 223:8 232:8 233:1 255:24 256:10 274:19 277:7,16 284:16 296:19 308:10 317:6
year 66:8 76:22 80:18 83:19 150:2 174:2 290:17 293:21 298:9 310:23 320:5,6 330:8 330:20 331:8
years 17:4 29:6 29:7 30:7 32:8 32:18 33:9 34:2 36:15 39:1 62:14 99:12 105:9,14 106:11,22 107:11 139:22 158:24 181:6 316:13,20
Yep 250:15
yesterday 18:10 19:10,13,16 22:23
York 1:16,17 2:15,20,20 13:9,9 15:19 17:3 26:13 44:15

Z

0

07 106:7

1

1 16:10 17:13,15 17:15 187:15 221:14 266:9 336:6
1/12/12 9:21
1/5/07 7:7
1/7/12 10:7
1:17-MD-2804 1:8
1:49 137:16
1:58 137:10
10 41:10 109:11 109:12,15 110:10 116:21 119:14 120:17 121:17,18 122:5 136:7 250:4
10/1/08 10:13
10/10/07 7:11
10:29 1:17 13:6
10:30 318:14
10119-3701 2:20
109 7:10
11 72:21 127:2
11/18/11 10:17
11/2/2009 239:23
11/9/12 11:6
11:49 88:4
11556 2:15
11791 15:19
12 138:3,20 273:22 275:20
12,000 67:17
12/19/12 11:10
12/27/07 8:7
12:06 88:9
127 7:13
12th 26:9
13 165:2 228:3
1301.74 6:18
1301.74(b) 9:10
137 7:17
14 5:7 171:4 207:5,6,7 287:12
15 206:20 230:20 276:23
15219 3:14
15th 276:24 277:3
16 7:14 138:21 176:2,20 240:13,21
164 7:19
16th 127:22
17 5:16 7:14 127:22 186:4,5 206:20
171 7:21
174 8:6
175 8:9
18 191:15 304:1 304:7
183 56:14
186 8:12
19 1:12 13:5 56:24 76:21 186:4 216:20 220:10 287:14 306:5 318:23 320:12
191 8:14
1970 92:6
1971 90:16
1976 298:9
1987 30:6 31:1,6
1996 17:7 26:19 27:18 29:13 30:6 31:1,6 32:4,15,21 36:15 55:14,21
1998 32:4,16 33:6
1999 29:8,9,13 30:3 36:15,22 38:6,11,19 42:2 89:8,9
19th 87:3
1st 55:21 84:14 299:22

2

2 25:22 64:24 77:1 99:15 206:24 207:10 265:24 266:11 266:12 267:10
2/1/12 10:21
2/10/11 9:13
2/6/08 8:18
2/7/07 7:22
20 83:15 116:13 117:7 125:6 225:23 227:8 336:20
200 1:16 13:8
2000 99:14 165:5 179:15 227:24
20001 3:4
2000s 88:16 99:15 163:23
2001 99:15
2002 33:17 99:18 101:4 139:20 140:8 140:12,24 141:11 150:2 210:23
2005 138:9,11 138:14,16,22 139:9 140:13 140:24 141:11 142:11 146:17 150:23 154:1 155:6,24 156:1 156:4 157:22 158:11 159:21 160:1,6 163:14 163:19 181:15

182:6 267:24
2006 39:23 71:13 165:6 166:17,18 170:18
2007 7:14 40:5 41:10 42:2 45:10 52:5,10 52:20 54:18 58:14 63:1 69:12,17,19 71:13 73:9 75:5,21 79:3,9 80:4 81:6,12 83:6,15 84:6 84:19 89:9 98:23 99:4,8 99:18 101:4 103:18,21 104:17 108:8,9 109:15 110:10 111:1,14,24 114:2,17 115:1 115:5,10 116:9 116:13,21 117:8 118:18 119:17,22 120:9 122:5 124:22 125:6 127:23 129:12 131:6,18 132:9 133:20 134:2 134:18 165:3 170:21 171:5 171:24 172:4 172:11 173:23 174:8 175:14 175:19 179:13 179:21 206:4 207:23 210:23 241:8,9,20 289:18 297:15
2007-2008 103:13
2008 33:22 72:4 72:14 77:7,14 77:20,21 78:3 78:4 80:22 83:22 84:19 98:24 176:20 176:22 178:13 178:14 179:16 181:6 184:1 185:22 187:18 189:7 190:7,15 190:24 191:8,9 191:17,21 192:7,21 196:21 200:9 200:17 202:17 217:12 220:11 220:16,19 223:14 225:11 226:4,4 228:2 228:3 232:7,22 232:24 296:23 297:2 299:22 306:5
2009 64:24 71:23 84:10,22 85:4,18 108:18 108:22 109:5 182:24 183:6,9 183:14,21,23 184:20 185:2,5 185:10 210:17 214:17 215:19 234:12,17 240:8,14,21 241:11,13 242:20 243:9 244:3 246:3,14 246:23 247:4 248:9 306:6 322:1
2010 287:14,14 289:21 317:1
2011 33:22 35:3 250:4 251:10 251:22 257:18 259:1 261:3 267:9,14 269:22 271:11 271:15,20 272:6 287:15 287:15 289:22 304:1,7 307:20 309:10
2012 17:7 26:9 26:20 56:21,24 59:8 86:1,9,24 87:1 229:22 275:9,20,24 276:23,24 277:13 278:4,7 278:16,18 286:12 289:18 290:17 293:9 304:13 311:24 314:14,24 317:1 318:24 320:12 329:21
2013 11:12 295:20 320:13 322:15 324:5 325:15 329:12 329:18 330:7
2016 210:17
2018 76:21
2019 1:12 13:6 333:15
202 3:4
203 56:2,8,10,11 56:16
21 6:18,20,21 9:10 39:23 234:1
212 2:21
213 3:20
214 2:10
216-9000 2:4
217-8800 3:10
21st 55:24 56:21
22 239:21 333:15
220 8:17
2200 2:8
225 8:20
227.0620 2:15
23 67:18 250:1
233 9:6
239 9:10
24 34:1 271:10
243-4000 3:20
249 9:12
25 5:18 287:14
27 165:5 174:8 286:3
271 9:15
275 9:18
277 9:20
27th 187:12
28 2:3 191:17,21 293:20
2800 2:9
286 10:6
29 297:8
293 10:10
29464 2:4
297 10:13
2nd 240:8,20

3

3 39:9,10 57:20 120:20 156:8 156:11 167:15 266:11
3:00 19:17
3:10 219:23
3:15-ish 19:18
3:29 220:4
30 303:22 334:16
303 10:17
307 10:20
31 287:15 307:6
31,000 307:20 309:9 310:23 312:24 313:13
31,000-a-year 312:20
313 11:6
318 11:9
31st 306:6 307:15
32 313:24
33 318:20
337 336:6
338-4683 3:15
35th 3:14
37th 2:20
39 5:20
397 15:18

4

4 55:4,13 230:20 242:11
4:44 296:10
4:54 296:15
40 294:18 295:6 297:21
400 2:14
412 3:15
44th 3:19
45 298:9 299:5
4950 3:9

5

5 64:18 78:21 84:11 120:24 121:1 179:12 180:14 240:4
5/11/09 9:7
5:28 332:5,8
516 2:15
55 6:6
55402 3:10
586N 3:3

6

6 67:19 76:16 84:10 220:16 220:18 271:11 271:14 273:22
6/12/12 9:18
60 294:17,22 295:19
612 3:10
613.2067 2:21
629100 10:21
64 6:9

662-5516 3:4
6th 278:6 289:17 289:18

7

7 40:5 89:22 171:5,24 206:4 207:1 287:15
7/19/18 6:13
740.8758 2:10
75201 2:9
76 6:13
777 3:19
7th 6:10 117:20 207:10

8

800 306:7
801 6:21
821 6:21
823 6:21
823(E) 207:15
843 2:4
850 3:3
877.370.3377 1:22
89 6:17,20

9

9 93:22 104:10 278:16 314:14
9/20/07 112:21
9/20/2007 121:4 121:21
9/27/06 7:19
9:00 19:16
90 3:9 29:7 210:7
9000 27:12,13 30:21,22 31:8 37:24
90017 3:20
917.591.5672 1:22
93 7:6
96 29:5,7
97 155:7
9th 84:14 278:18